554105 CMR 130.000: HOSPITAL LICENSURE

Section

130.000: continued

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130.001: Purpose

105 CMR 130.000 sets forth standards for the maintenance and operation of hospitals.

130.002: Authority

105 CMR 130.000 is adopted under the authority of M.G.L. c. 111, §§ 3 and 51 through 56.

130.003: Citation

105 CMR 130.000 shall be known and may be cited as 105 CMR 130.000: *Hospital Licensure*.

130.010: Scope

105 CMR 130.000 applies to every hospital subject to licensure under M.G.L. c. 111, §§ 51 through 56, except as stated herein.

130.550: Issuance of an Amended Hospital License

Upon receipt of satisfactory written documentation of FAHCT accreditation by the type of transplants performed, the Department shall issue an amended hospital license which indicates that the hospital is authorized to perform hematopoietic progenitor/stem cell transplantation (allogeneic and/or autologous for adult and/or pediatric patients). For multiple hospitals that form one program, each hospital shall have the service added to its license. In such cases, the license will indicate that the hospital is part of a multiple hospital program.

130.560: Renewal of Hematopoietic Progenitor/Stem Cell Transplantation Program Licensure

The hospital shall apply for renewal of its license to perform hematopoietic progenitor/stem cell transplantation at the time of renewal of the hospital's license.

130.570: Reporting to the Department of Public Health

As a condition of maintenance and renewal of licensure of the program, the hospital shall submit information as requested by the Department regarding the transplantation service.

130.580: Denial, Revocation or Refusal to Renew Licensure of the Transplantation Program Based on Lack of Accreditation by FAHCT

Loss or denial of accreditation shall be reported in writing to the Department within 48 hours of receipt of such notice to the hospital from FAHCT. Failure to receive or maintain accreditation by FAHCT shall result in the denial, revocation or refusal to renew the licensure of the transplantation program without further hearing.

130.601: Definitions

The following definitions apply in 105 CMR 130.000 when used with regard to maternal and newborn services:

Antepartum Patient shall mean any pregnant woman who is characterized as having a high-risk obstetric complication or a pregnant patient with a medical or surgical condition.

Birthing Room shall mean a room designed to provide family-centered care in a "homelike" environment for low-risk mothers throughout the labor, delivery and immediate recovery periods.

Certified Nurse Midwife shall mean an individual authorized by the Board of Registration in Nursing under M.G.L. c. 112, § 80C and authorized to practice as a nurse-midwife pursuant to 244 CMR 4.00 *et seq*.

Cesarean/Delivery Room shall mean a room staffed and equipped to handle low-risk to high-risk deliveries, including cesarean births, and have capabilities of administering all forms of anesthesia, including inhalation agents.

Clinical Nurse Specialist shall mean a registered nurse with a current license from the Massachusetts Board of Registration in Nursing. For the purpose of 105 CMR 130.601 through 130.650, the clinical nurse specialist must be master's prepared with clinical expertise in advance nursing practice in the specialty area of maternal or neonatal health.

Critical Care Obstetrics Team shall mean a team including representatives from the following available 24 hours a day, seven days a week: Maternal-fetal medicine consultant; in-house obstetrician; in-house nursing staff with demonstrated competency in critical care; in-house anesthesia; in-house neonatologist and other medical specialties available, as needed, including at a minimum infectious disease, pulmonary, surgery, and cardiology.

Continuing Care Nursery shall mean a nursery that is specially equipped and staffed to offer a variety of specialized services as specified in 105 CMR 130.630(E) to mild or moderately

ill infants born at the level IB hospital or to retrotransferred stable - growing or recovery infants who do not require intensive or special care.

130.601: continued

Designated Service Levels shall mean levels of care based on services provided by the hospital as approved by the Department of Public Health.

Family-centered Care shall mean a method of providing services that fosters the establishment and maintenance of parent-newborn-family relationships. The family may consist of the father, mother and child and/or include other identified support persons (biologically or nonbiologically related) for the mother and infant.

Family Practitioner shall mean a physician licensed by the Massachusetts Board of Registration in Medicine who has completed a residency in family medicine, which includes training in internal medicine, pediatrics and obstetrics and is certified or an active candidate for certification by the American Board of Family Practice.

Freestanding Pediatric Hospital with Neonatal Subspecialty Services shall mean a service that has the capabilities to provide care to moderately to severely ill neonates who require neonatal intensive care services and to newborns with actual medical problems.

Gynecology Patient shall mean any woman with or suspected of having a health problem related to her reproductive organs.

Labor Room shall mean an area in which the mother experiences the first stage of labor.

Labor-delivery Suite shall mean that part of a maternal and newborn service used to care for patients during labor, delivery and recovery. It shall include physically contiguous labor room(s), cesarean/delivery room(s) and ancillary facilities.

Labor-delivery-recovery Room (LDR) shall mean a room designed, staffed and equipped to care for mothers, newborns and their families throughout the labor, delivery and recovery periods.

Labor-delivery-recovery-postpartum Room (LDRP or Single-Room Maternity Care) shall mean a room designed, staffed and equipped to care for mothers, newborns and their families throughout the labor, delivery, recovery and postpartum periods.

Lactation Consultant shall mean an individual certified as an International Board Certified Lactation Consultant (IBCLC) or an individual with equivalent training and experience.

Level I - Community-based Maternal and Newborn Service shall mean a community-based maternal and newborn service including Level IA and Level IB services that meets the requirements in 105 CMR 130.630.

Level I A service shall mean a community-based maternal and newborn service with a well newborn nursery that provides for the care and management of maternal conditions consistent with American College of Obstetricians and Gynecologists (ACOG) guidelines, including management of pregnancies judged unlikely to deliver before 35 weeks gestation.

Level IB Service shall mean a Level I community-based maternal and newborn service with a continuing care nursery that provides for the care and management of maternal conditions consistent with ACOG guidelines, including management of pregnancies judged unlikely to deliver before 35 weeks gestation.

Level II Service shall mean a community-based maternal and newborn service with a Special Care Nursery including Level IIA and Level IIB services that meets the requirements in 105 CMR 130.640.

Level II A Service shall mean a community-based Level II maternal and newborn service with a Special Care Nursery that provides for the care and management of maternal conditions consistent with ACOG guidelines, including management of pregnancies judged unlikely to deliver before 34 weeks gestation.

130.601: continued

Level IIB Service shall mean a community-based maternal and newborn service with a Special Care Nursery that provides for the care and management of maternal conditions consistent with ACOG guidelines, including management of pregnancies judged unlikely to deliver before 32 weeks gestation and that meets the requirements in 105 CMR 130.640.

Level III Maternal and Newborn Service shall mean a maternal and newborn service that provides for the care and management of maternal conditions consistent with ACOG guidelines, including pregnancies at all gestational ages and that meets the requirements in 105 CMR 130.650.

Maternal-fetal Medicine Specialist shall mean an obstetrician/gynecologist who is licensed by the Massachusetts Board of Registration in Medicine and is certified or is an active candidate for certification in the subspecialty of maternal-fetal medicine by the American Board of Obstetrics and Gynecology.

Maternal and Newborn Service shall mean that part of the hospital in which care is routinely delivered to mothers and newborns.

Neonatal Fellow shall mean a physician licensed by the Massachusetts Board of Registration in Medicine who is completing a fellowship in neonatology.

Neonatal Intensive Care Unit shall mean a unit located either in a hospital with a Level III maternal and newborn service or a freestanding pediatric hospital with neonatalogy specialty services that provides a comprehensive range of specialty and subspecialty services to severely ill infants.

Neonatal Nurse Practitioner shall mean an individual authorized by the Massachusetts Board of Registration in Nursing under M.G.L. c. 112, § 80B and authorized to practice as a nurse practitioner pursuant to 244 CMR 4.00 *et. seq* who holds certification as a neonatal nurse practitioner from a nationally recognized accrediting body acceptable to the Board.

Neonatal Resuscitation Program (NRP) shall mean the American Academy of Pediatrics' course designed to teach resuscitation of the newborn.

Neonatologist shall mean a physician licensed by the Massachusetts Board of Registration in Medicine who is either certified or an active candidate for certification in neonatology by the American Board of Pediatrics.

Obstetrician shall mean a physician licensed by the Massachusetts Board of Registration in Medicine and who is either certified or an active candidate for certification by the American Board of Obstetrics and Gynecology.

Pediatrician shall mean a physician licensed by the Massachusetts Board of Registration in Medicine who is either certified or an active candidate for certification in pediatrics by the American Board of Pediatrics.

Postpartum Unit shall mean that part of a maternal and newborn service that is used exclusively for postpartum care. Postpartum beds include beds located in labor-delivery-recovery-postpartum rooms.

Recovery Area shall mean a specifically designated area within the labor-delivery suite used to care for patients recovering immediately after delivery.

Recovery Infant shall mean an infant who required acute care services for diagnosis and treatment, whose acute phase of illness has passed, and who now needs limited therapeutic intervention prior to discharge.

Retrotransferred Infant shall mean an infant who required transfer to a more acute level facility for diagnosis or treatment not available in the birth hospital, who no longer requires these services, and is transferred back to the birth hospital or to another hospital with the level of service meeting his/her needs.

130.601: continued

Risk Assessment of the Infant shall mean the process of evaluating the newborn to determine whether he/she has special risks or combination of risks for adjustment to extrauterine life, health or survival in order to determine the need for specialized services, which includes a review of social, economic, genetic, and medical history findings prior to delivery or within the newborn period.

Risk Assessment of the Maternal Patient shall mean the process of medically evaluating the mother to determine whether she has special risks or combination of risks to her own health and well-being or to that of the fetus in order to determine the need for specialized services and which includes a review of social, economic, genetic and/or medical conditions during the antepartal, intrapartal and/or postpartal periods.

Special Care Nursery shall mean a nursery that is specially equipped and staffed to offer a variety of specialized services to moderately ill infants who do not require intensive care.

Stable-growing Infant shall mean the medically stable infant with a low birth weight who requires only a weight increase to be ready for discharge.

Transfer Infant shall mean any infant who is transferred from the birth hospital because he/she requires acute services for diagnosis and treatment not available at the birth hospital.

Well Newborn Nursery shall mean a room housing newborns who do not need continuing care, special care of intensive care newborn services.

130.605: Department Designation of Level of Maternal and Newborn Care in a Hospital

(A) The Department shall designate the level of maternal and newborn care of each hospital subject to Department licensure that provides maternal and/or newborn services as defined in 105 CMR 130.020.

(B) As directed by the Department, each hospital with maternal and/or newborn services shall file an application with the Department identifying the level of maternal and/or newborn services for which the hospital requests designation.

(C) The Department shall base such designation upon documentation submitted by each hospital regarding its maternal and/or newborn services and/or on-site evaluations by Department staff to determine compliance with the requirements of that level. The designation process is not intended to supersede the Department's authority to determine what constitutes a major service or a substantial change in service for determination of need purposes.

(D) After the initial designation, the hospital shall re-apply for designation of its maternal and/ or newborn services each time that it applies for renewal of its hospital license.

130.610: Establishment of the Statewide Perinatal Advisory Committee

The Department shall establish a state Perinatal Advisory Committee to advise the Department on issues related to 105 CMR 130.615 through 130.628 (Maternal and Newborn Services). This Committee's membership shall be multidisciplinary. It shall include but not necessarily be limited to one or more members of the following groups: physicians, nurses, including nurse practitioners and nurse midwives, hospital administrators, and consumers. It shall be representative of the various parts of the state and all levels of perinatal care.

The Committee may develop operating procedures agreed upon by the Department that includes the opportunity for the regular rotation of committee members.

130 615: Patient/Family Services

(A) The mother and infant shall receive care in the facility providing the level of service required for their unique medical needs.

130.615: continued

(B) Each hospital with a maternal and newborn service shall provide prenatal, postnatal and family-planning services either directly or through referral to an outside agency, including the following:

(1) Preparation for the birthing experience for the mother, her family and/or significant other(s).

(2) Organized family-education program with associated written and/or multimedia health instructional materials including, but not limited to:

(a) Normal maternal care such as nutrition, rest and other basic needs.

(b) Signs and symptoms of pre-term labor by 20 weeks, if applicable.

(c) Normal newborn care and well child care, including recommended immunization and developmental assessment schedules and infant safety, including information about shaken baby syndrome.

(d) State newborn blood screening information and materials provided at the time of admission prior to screening.

(e) Abnormal symptoms in mother and/or infant for which the family should seek medical attention, including infant jaundice.

(f) Anticipatory guidance and available resources for peripartum mental health issues and family adjustment issues.

(g) Family planning.

(h) Dangers of second-hand smoke.

(3) Infant feeding instruction and support during hospitalization and provision of information on resources to assist the mother and family after discharge, including, for breast feeding mothers, community-based lactation consultant resources and availability of breast pumps.

(C) Health education materials and activities shall be available in the major languages identified through the acute hospital's language needs assessment required under 105 CMR 130.1103(A) and literacy levels of the population served by the maternal and newborn service.

(D) The hospital shall have visitation policies for all service levels that promote parent-infant contact and maintenance of the family unit, while providing safety and privacy. These written policies shall be made available to families.

(1) Hospitals shall provide educational information to all visitors indicating that the following persons should not visit: those who have been exposed to or have manifestation of communicable diseases for which the newborn is at particular risk, *e.g.*, impetigo, active tuberculosis, acute respiratory disease as well as vaccine-preventable diseases, particularly measles, mumps, rubella, pertussis, varicella and influenza.

(2) Siblings shall be permitted to visit the mother and newborn on a daily basis in accordance with written hospital visitation policy.

(3) Policies for other visitors shall be formulated primarily for the support and comfort of mothers and infants.

(4) The hospital shall have a policy to address the safety and security of mothers and infants.

(E) The hospital shall establish policies to ensure that the staff provide ongoing information to families about the condition and progress of mother and/or infant. The policies shall also include a process to assist families in obtaining ongoing information about the condition of the infant who has been transferred to another level of care. For the limited-English-proficient population, the hospital shall ensure that timely interpreter services are available. Services using nurse practitioners or pediatric residents shall inform families of the role and scope of clinical responsibilities of these health care providers.

(F) Culturally and linguistically appropriate nutritional consultation shall be available for mothers and infants.

(G) Culturally and linguistically appropriate social work services shall be available for mothers and infants.

130.615: continued

(H) Each maternal and newborn service shall have written protocols for the hospital management, support, and discharge planning of patients from identified groups in the population served by the facility who have special needs, *e.g.*, adolescents, and mothers with known physical or cognitive impairments, substance abuse, psychiatric diagnoses or psychosocial concerns.

(I) Each service shall have a written policy that provides for discharge planning and referrals to community agencies and healthcare providers, including lactation consultants as needed.

(J) Mothers of babies with special health needs shall receive information about appropriate resources such as early intervention, self-help groups, and other community contacts as soon as possible after delivery.

(K) Each service shall provide support and referral for the family experiencing perinatal grief because of the death of a neonate. All families shall be given the opportunity to see, hold and participate in the care of their infant during and after the dying process.

(L) The maternal and newborn service shall provide information about the Women, Infants and Children (WIC) program's benefits and services to all mothers. As appropriate, staff shall refer a mother to the WIC program closest to her residence.

130.616: Administration and Staffing

(A) Perinatal Committee.

(1) Each maternal and newborn service shall establish a multidisciplinary perinatal committee or its equivalent responsible for developing a coordinated approach to maternal and newborn care including but not limited to the following:

(a) Developing a statement of goals and objectives of family-centered care.

(b) Long-range program planning.

(c) Establishing, approving, reviewing and planning the implementation of policies and procedures.

(d) Reviewing and evaluating process and outcome of maternal and newborn care delivered by the service, including appropriateness of multidisciplinary staffing patterns to ensure safe patient care.

(e) Reviewing service data and statistics.

(f) Providing a mechanism to encourage and obtain community input on the service.

(g) Participating in the evaluation of staff education needs.

(2) The committee shall meet at least quarterly and include physician and nurse leaders from both the maternal and newborn services and representatives from other services as appropriate.

(B) Written Collaboration and Transfer Agreements.

(1) Each hospital with a maternal and newborn service that is not designated as a Level III service shall develop a written collaboration/transfer agreement with at least one primary Level III maternal and newborn service. The agreement shall include provisions for consultation; guidelines for maternal and newborn transfer, including provision of relevant medical information and ongoing patient-centered communications before, during and after transport; and provision for professional educational offerings.

(2) In its collaboration/transfer agreement with a level III service, a hospital that is designated by the Department as a level II maternal and newborn service and that retains neonatal nurse practitioners to provide on-site delivery room and special care nursery coverage shall include provisions for administrative and clinical collaboration specific to the neonatal nurse practitioners. At a minimum specific provisions shall include the planned schedule of rotation of the neonatal nurse practitioner to the level III service and the mechanism for the periodic evaluation of the neonatal nurse practitioner's performance as required under 105 CMR 130.640(E)(3)(b)(iii).

(3) Collaboration/transfer agreements between hospitals that regularly transfer patients shall include provisions for monitoring the quality of care provided to transfers with a focus on outcomes.

130.616: continued

(4) Guidelines for maternal and newborn transfer shall reflect recommendations from the quality assurance activities. The guidelines shall address the following: initiation of transfer; acceptance of transfer; delineation of responsibilities of referring hospital, transport team and receiving hospital; patient consent; transfer procedures and retro-transfer policy and procedures.

(5) The Level III hospital receiving a request for a transfer shall accept all medically appropriate obstetrical and neonatal patients for which it has the resources to provide the appropriate level of care. If a bed or appropriate resources are not available, upon the request of the referring hospital, the Level III hospital shall offer assistance and advice on possible alternative Level III hospitals for transfer.

(6) The Level III hospital receiving transfers shall return maternal and neonatal patients to the transferring hospital when it is clinically appropriate to do so. The hospital shall inform the patient and/or patient's family that the patient may be transferred back when such a retro-transfer is medically appropriate.

(7) A maternal and newborn center located close to a level III service in another state may develop an agreement with that center, provided the center meets the applicable regulations for that state.

(8) Copies of current written collaboration/transfer agreements shall be submitted to the Department upon request.

(C) Administrative Policies. Each maternal and newborn service shall develop and implement written administrative policies that include provisions for the following:

(1) Staff privileges granted to each physician, nurse midwife and each nurse practicing in an advanced practice role shall specify those areas in which his/her practice is limited and/or requires consultation before therapeutic intervention.

(2) Documentation of informed consent for both maternal and newborn care.

(3) On-site availability 24 hours a day, of at least one professional staff member who is a provider of neonatal resuscitation and trained by a recognized program, such as the American Academy of Pediatrics' Neonatal Resuscitation Program (NRP).

(4) Management of high-risk mothers and newborns including identification of high risk patients and consultation with appropriate specialists for the purpose of determining treatment and/or the need to transfer to the hospital's specialized medical, surgical or critical care services or to another facility offering the level of care required by the patient. Such policies shall include use of appropriate alternative facilities, if beds in the usual affiliated transfer institution are not available. Such policies shall address maintaining family-centered care.

(5) Placement of and care of:

(a) antenatal patients (hospitalized for pregnancy-related conditions) on the maternal and newborn service; and

(b) antenatal patients hospitalized for medical/surgical conditions that are not pregnancy-related.

(6) Admission of the previously-discharged (to home), or retrotransferred recovery stable-growing infant under the following circumstances:

(a) The infant previously discharged to home may be readmitted to the newborn nursery provided that the infant is within two weeks of discharge from that nursery, has a noninfectious condition and is approved for readmission by the medical director of the newborn service and the maternal and newborn nursing administrator or their designee(s).

(b) The retrotransferred recovery infant may be admitted to the newborn nursery upon written order of the attending physician and approval of the medical director of the newborn service and the maternal and newborn nursing administrator or their designee(s).

(c) The newborn service may admit a retrotransferred recovery infant who was not born at that hospital, providing the hospital offers the level of service required by the infant and is geographically close to the parents.

(d) The retrotransferred infant who is transferred from a hospital unit with known multi-drug-organism colonization or infection, including methicillin-resistant staphylococcus aureus, shall be managed with contact precautions in accordance with the Centers for Disease Control and Prevention guidance until the presence of infection or colonization with an antibiotic-resistant organism has been ruled out.

130.616: continued

(7) Provision for a written discharge summary to another maternal and newborn service at the time of the patient's transfer or to the primary care provider at the time of the patient's discharge. The summary shall include diagnosis and treatment provided.

(D) Patient Care Policies. Each maternal and newborn service shall develop and implement written patient care policies and procedures, supported by evidence based resources, which shall include provisions for the following:

(1) Triage of patients presenting to the service to establish the diagnosis of labor, need for admission, transfer and/or other care management.

(2) Communication and decision making responsibilities with specified chain of command.

(3) Pain management, including the use of non pharmacological support techniques, analgesic medication and parenteral therapy. Routine standing orders shall not be permitted.

(4) Fetal assessment modalities including the use of electronic fetal monitoring and auscultation with guidelines for interpretation.

(5) Elective and emergency cesarean birth.

(6) Criteria for induction and augmentation of labor.

(7) Initiation and management of epidural analgesia and regional anesthesia.

(8) Criteria for when the presence of a pediatrician and specialized personnel are required at birth.

(9) Care of the mother in the immediate post partum period, including immediate post-surgical recovery care.

(10) Immediate nursing assessment of the newborn by a registered nurse with specific clinical criteria for notifying a pediatric provider.

(11) Support of lactation initiation and maintenance for mothers who choose breast feeding. Such policies shall provide for the following:

(a) No standing orders for antilactation drugs.

(b) Unless medically contraindicated, encouragement of breastfeeding as soon after birth as the baby is interested. A mother separated from her infant shall be assisted to initiate and maintain her milk production.

(c) Frequent nursing periods, based on the infant's needs.

(d) Supplemental bottle feeding for medical reasons or on request of the mother only.

(e) Sample formula and/or formula equipment distributed to breast-feeding mothers only when an individual physician order is written or on the request of the mother.

(12) Care of the Newborn. Such policies shall provide for the following:

(a) Apgar scoring.

(b) Thermoregulation, including skin-to-skin contact when appropriate.

(c) Eye prophylaxis for ophthalmia neonatorum.

(d) Collection of cord blood sample.

(e) Vitamin K administration.

(f) Infant security policies and procedures developed in conjunction with the hospital’s security and pediatric departments. At a minimum, the policy shall address:

(i) a process for identifying the newborn at the time of delivery;

(ii) use of an acceptable identification system;

(iii) procedure for rebanding an infant;

(iv) identification of individuals who can remove a newborn from the nursery;

(v) visitation policies outlining who is allowed to visit and when; and

(vi) a plan for educating parents regarding the security procedures.

(g) Promotion of parent-newborn contact.

(h) Infant feeding (including flexible schedule per parent's request), output measurement and skin-to-skin care.

(i) Comfort measures and reduction of pain and trauma during invasive procedures.

(j) Complete physical examination by a physician within 24 hours of birth or upon admission, including infants who are retrotransferred.

(k) Stabilization and management of the infant requiring transfer including the opportunity for the family to see and touch the infant before transfer.

(l) Hearing screening.

(m) Newborn blood screening required by statute.

(n) Appropriate administration of hepatitis B vaccine and hepatitis B immune globulin to all infants according to the recommendation of the Centers for Disease Control Advisory Committee on Immunization Practices and the Massachusetts Immunization Program.

130.616: continued

(13) Planning for discharge, including documentation of follow-up care arrangements and referral to appropriate community services and providers for both mother and infant.

(14) Admission and/or treatment of patients who have delivered outside of the maternal and newborn service or hospital, including home births.

(15) Use of the maternity service for gynecology patients. Gynecology patients shall not be routinely cared for on a maternity unit; however, in the event that they are placed on the unit, they shall be in rooms separate from maternity patients and the following shall be required:

(a) Provision for the availability of maternity beds to meet patient needs.

(b) Admission guidelines with exclusionary criteria for patients:

(i) requiring radioactive implants;

(ii) who have active infection or are colonized with a potentially virulent or drug resistant organism that would put others at risk, for which appropriate and consistent use of recommended infection control practices cannot be assured; or

(iii) requiring significant medical or surgical care in addition to gynecologic care;

(iv) visiting policies shall be consistent with those on the maternity service.

(16) Protocols to assure that the care of obstetrical patients hospitalized for medical/surgical conditions is coordinated, including consultation with obstetrical services medical and nursing staff.

(17) Offering and administering a dose of measles-mumps-rubella (MMR) vaccine to all mothers who are rubella antibody negative prior to discharge.

(18) Policies for the safe and secure storage and handling of infant feedings, formula and breast milk, including policies to ensure the correct labeling and identification af all infant feeding.

(E) Quality Assurance and Education Program.

(1) Each maternal and newborn service shall have an ongoing documented quality assurance program including problem identification, action plans, evaluation and follow-up. A multi-disciplinary approach shall be required.

(2) The quality assurance program shall include at least an annual review of transfer cases, management of cases, and educational programs and protocols among facilities that transport maternal and neonatal patients to one another pursuant to collaboration/transfer agreements.

(3) Outcome statistics including neonatal and perinatal mortality, as well as appropriateness of neonatal and maternal transfers, shall be compiled in a standardized manner and reviewed at a minimum on a quarterly basis by the hospital perinatal committee. Neonatal and maternal deaths after transfer or discharge from the facility (within first 28 days of birth) shall be included in the statistics.

(4) The quality assurance program shall include an annual Hearing Screening Program Evaluation of critical performance data, including but not limited to, number of live births, number of infants screened, number of infants who passed the screening, number of infants who did not pass the screening in the right ear, number of infants who did not pass the screening in the left ear, number of infants who did not pass the screening in both ears, number of infants who missed screening or were unsuccessfully screened, the number of infants referred for diagnostic testing, and the number of parents or guardians who refused screening.

(F) Nurse Staffing. The Maternal and Newborn service shall meet the following requirements:

(1) A registered nurse shall assess the needs, plan the care and evaluate the care delivery including the health education of each patient.

(2) A registered nurse shall observe and care for the mother, fetus and newborn during the labor, delivery and recovery periods.

(3) A registered nurse who has successfully completed a recognized program in neonatal resuscitation, such as the Neonatal Resuscitation Program (NRP), shall be present during the delivery. A second registered nurse shall be immediately available as additional support until the mother and infant are stabilized.

(4) A registered nurse shall complete an initial newborn nursing assessment and shall be responsible for notifying the physician of any abnormalities or problems.

(5) A registered nurse shall be on duty in each patient care unit on every shift.

130.616: continued

(6) The hospital shall ensure that all licensed nursing staff caring for maternal and newborn patients have demonstrated current competency in providing care in the specialty area. All licensed nursing staff shall receive orientation and periodic in-service education related to the current best practices for maternal and newborn care including training or documented skill in at least the following areas:

(a) Evaluation of the condition of the mother, fetus and newborn.

(b) Assessment of risk during the labor, delivery, recovery and postpartum periods.

(c) Fetal assessment modalities including use of electronic fetal monitor, auscultation tools, interpretation of fetal heart-rate patterns and initiation of appropriate nursing interventions for non-reassuring patterns (for nurses caring for pregnant women).

(d) Nursing management of emergency situations that specifies communication and decision-making responsibilities and chain of command.

(e) Adult and newborn resuscitation.

(f) Immediate care and assessment of the newborn.

(g) Family-centered care that is culturally and linguistically appropriate.

(h) Support of the normal processes of labor and birth.

(i) Mother and infant security.

(j) Initiation and support of lactation.

(7) The licensed nursing staff shall receive documented retraining in adult and neonatal cardio-pulmonary resuscitation every two years and annual mock code drills. Each maternal and newborn service shall provide licensed nursing staff with continuing education in specialty areas of the service.

(G) Lactation Care and Services.

(1) Each hospital shall deliver culturally and linguistically appropriate lactation care and services by staff members with knowledge and experience in lactation management. At a minimum, each hospital shall provide every mother and infant requiring advanced lactation support with ongoing consultation during the hospital stay from an International Board Certified Lactation Consultant (IBCLC) or an individual with equivalent training and experience.

(2) Each maternal and newborn service shall develop written, evidence-based breastfeeding policies and procedures and include these in staff education and competency reviews.

(3) An educational program of lactation support for maternal and newborn staff shall be offered by qualified staff and shall address the following areas:

(a) The nutritional and physiological aspects of human lactation.

(b) Positioning of mother and infant to promote effective sucking, milk release and production.

(c) Practices to avoid, recognize and treat common breastfeeding complications.

(d) Nutritional needs of the mother during lactation and monitoring the nutritional needs of the infant.

(e) Safe techniques for milk expression and storage of milk.

(f) Information about community support services available to the family after discharge.

(g) Cultural values related to breastfeeding.

130.617: Ancillary Services

(A) Laboratory. The clinical laboratory services available for maternal and newborn patients shall be defined by the Chief of Laboratory Services in consultation with the Chief(s) of both Maternal and Newborn Services and the hospital administrator or his or her designee.

(B) Radiology.

(1) The diagnostic imaging and radiological procedures available for maternal and newborn patients shall be defined by the Chief of Radiology in consultation with the Chief(s) of both the Maternal and Newborn Services and the hospital administrator or his or her designee.

130.617: continued

(2) The maternal and newborn service shall have written policies for diagnostic radiologic examination of pregnant patients aimed at preventing excessive radiation exposure to the fetus and mother.
(3) A written request for a diagnostic radiologic examination of a pregnant patient shall clearly indicate to the person taking the x-ray that the patient is pregnant.
(4) Each radiologic service shall have an orientation training program and protocols for personnel performing infant x-rays, which address at a minimum safe positioning of the newborn, measures to minimize x-ray exposure and prevention of x-ray exposure to the infant's gonads.

130.618: Environment: General Requirements

(A) Unless otherwise specified, new construction or alterations/additions to existing services shall meet the requirements of 105 CMR 130.107.

(B) The maternal and newborn service shall be self-contained and discrete from other hospital services and be situated so as to accommodate patient flow without passing through other functional areas of the hospital. There shall be limited access to the service.

(C) All equipment, furnishings and decorations in the maternal and newborn service shall be made of washable materials.

(D) The environment shall foster family-centered care including provisions for:
(1) Mothers and infants to room-in together 24 hours a day.
(2) Respect for the privacy of all mothers and families.
(3) Visitation for father or significant other(s) 24 hours a day.
(4) Accommodating visitors.
(5) Private area for mothers to nurse and/or use breast pump.
(6) Rapid reunion of mother and infant after medical/surgical procedures, including cesarean section and circumcision.

(E) Maternal and newborn services shall have the capability to provide care during labor, delivery, recovery and post-partum periods. Maternal and newborn services may have any one or a combination of several functional configurations including labor-delivery suites, birthing rooms, combination labor-delivery-recovery rooms and labor-delivery-recovery-postpartum rooms. Sufficient equipment shall be available to accommodate rooms in the event of simultaneous use. Each facility shall have at least one delivery room equipped for cesarean births. Cesarean births shall be performed in this room.

(F) The maternal and newborn service shall have appropriate resources and facilities to care for antepartum patients requiring stabilization, hospitalization, or transfer for obstetrical conditions.

(G) Antepartum facilities shall be designed to ensure that outpatient areas are separate from inpatient service areas.

130.619: Labor-delivery Suite

(A) Labor Room.
(1) At least two labor beds shall be provided for each delivery room. (Birthing room; labor, delivery, recovery room; and labor, delivery, recovery and post-partum room beds may be substituted for labor beds.)
(2) Construction of new units or alterations or additions to existing maternal and newborn units begun on or after April 1, 2006 shall provide a minimum of 120 square feet per bed in labor rooms.
(3) Labor rooms shall not accommodate more than two mothers. Partitions or curtains shall be provided to insure privacy for multiple-occupancy rooms.
(4) Labor rooms shall have the traditional hospital wall covering and furnishings or an attractive comfortable "homelike" family-centered decor.
(5) The labor room shall contain or have access to toilet and shower facilities.
(6) Each labor room shall contain the following:

130.619: continued

(a) Nurse call system.
(b) Emergency call or intercommunication system.
(c) Oxygen outlet(s).
(d) Suction outlet(s).
(e) Sphygmomanometer with adult stethoscopes.
(f) Fetoscope or instrument for fetal auscultation.
(g) Clock with sweep second hand.
(h) Lighting for examinations.
(i) Bed for each patient.
(j) Seating for family members.
(k) Functional source of emergency electrical power.

(7) Each labor room shall have readily available:
(a) Handwashing units with hands-free controls.
(b) Emergency delivery kit.
(c) Resuscitation medications and equipment for both mother and infant.
(d) Electronic fetal monitoring equipment.

(8) All facilities, furnishings and equipment shall be washable.

(9) The labor room shall have access to a delivery room for emergency cesarean birth management.

(10) The maternal and newborn service shall designate adequate and appropriate space for labor triage.

(B) Cesarean/Delivery Room.

(1) The cesarean/delivery room shall meet the infection control standards of the hospital's operating rooms.

(2) Additional surgical procedures limited to pregnancy related conditions only, such as dilatation and curettage and postpartum tubal ligations, may be performed within the cesarean/delivery room.

(3) Construction of new units or alterations or additions to existing maternal and newborn units begun on or after April 1, 2006 shall provide at least 400 square feet of space in each cesarean/delivery room, except that such rooms that are not used for cesarean births shall contain at least 300 square feet.

(4) Environmental requirements for the cesarean/delivery room shall include:
(a) Adequate lighting for vaginal and cesarean births.
(b) Temperature control to prevent chilling of mother and newborn.
(c) Functional source of emergency electrical power.
(d) Oxygen and suction outlets for both mother and newborn.
(e) Emergency call system.
(f) Scrub sinks with hands-free controls in or adjacent to the room.
(g) Wall clock with sweep second hand.
(h) Mirrors for mothers to observe births.

(5) The cesarean/delivery room shall contain at least the following equipment:
(a) Delivery bed permitting variation in position for birth as well as anesthesia administration.
(b) Facilities for both regional and inhalation anesthesia.
(c) Immediate availability of adult and newborn resuscitation equipment including the following:
(i) Emergency medications.
(ii) Airway and intubation instruments.
(iii) Defibrillator.
(iv) Cardiac monitor.
(v) Oxygen administration equipment and oxygen saturation monitor.
(vi) Blood and intravenous administration sets.
(d) Heated, temperature controlled neonatal examination and resuscitation bed.
(e) Instruments for vaginal delivery, repair of lacerations, cesarean birth and management of obstetric emergencies.
(f) Infant identification materials.
(g) Equipment for clamping of the umbilical cord.
(h) Blanket warmer in or adjacent to the room.

130.619: continued

(i) Fluid warmer.
(j) Availability of continuous internal and external fetal monitoring and auscultation tool.

(C) Additional Equipment and Facilities. The labor/delivery suite shall contain:
(1) Access to radiologic viewboxes or digital imaging.
(2) Access to stretcher with side rails.
(3) Adequate clean storage and preparation area.
(4) Ready access to sterilization facilities.
(5) At least one soiled workroom with adequate space and facilities for cleaning equipment.
(6) Sleeping, shower, locker, lounge and toilet facilities for staff, separate from patients' area.
(7) Documentation area for administrative functions.
(8) Lounge accessible to patients and visitors.

(D) Recovery Area. Each maternal and newborn service that provides a separate recovery area shall meet the following requirements:
(1) Hospital policy shall state the types of patient conditions requiring admission to the recovery area.
(2) Each recovery area shall contain at least two beds and the following:
(a) Suction and oxygen outlets for each bed.
(b) Monitoring equipment appropriate to post anesthesia care.
(3) Emergency medications and equipment shall be immediately accessible to the recovery area.
(4) The care of the mother and newborn during the recovery period shall be under the direct observation of a registered nurse.
(5) Provisions shall be made to maintain the family unit during the recovery period.

130.620: Birthing Room

If the services include birthing room(s), the birthing room(s) shall meet all the requirements of a labor, delivery, recovery room (LDR) in 105 CMR 130.621.

130.621: Labor-delivery - Recovery Room

(A) There shall be written policies and procedures for the labor-delivery-recovery room that shall include, at a minimum, provisions for the following:
(1) Admission criteria.
(2) Criteria for transfer to the cesarean/delivery birth room.
(3) Restriction of anesthesia to local or regional modes.
(4) Care of the normal newborn including the minimum length of time the infant remains in the labor-delivery-recovery room.

(B) The labor-delivery-recovery room may be located outside the labor-delivery suite but shall be within the maternity unit so the patient may be transferred to the cesarean/delivery room without having to pass through other functional areas of the hospital outside the maternity service and so that infant security is maintained.

(C) Construction of new units or alterations or additions to existing maternal and newborn units begun on or after April 1, 2006 shall provide a minimum of 250 square feet of floor space for each labor-delivery-recovery room.

(D) The labor-delivery-recovery room shall have single patient occupancy.

(E) Each labor-delivery-recovery room shall contain or have access to private toilet and shower or tub facilities. If tub facilities are provided, there shall be at least a three foot clearance on two sides and at the end of the tub.

130.621: continued

(F) Each labor-delivery-recovery room shall contain the following:
(1) Nurse call system.
(2) Emergency call or intercommunication system.
(3) Oxygen outlet(s).
(4) Suction outlet(s).
(5) Sphygmomanometer with adult stethoscopes.
(6) Continuous vital sign monitoring equipment for the mother (when regional anesthesia is used).
(7) Equipment for the administration of local and regional anesthesia when these forms of anesthesia are indicated.
(8) Fetoscope or a means of evaluating fetal heart rate.
(9) Emergency delivery kit.
(10) Clock with sweep second hand.
(11) Adjustable lighting adequate for examinations.
(12) Bed.
(13) Adequate seating for family members.
(14) Functional source of emergency electric power.

(G) (1) Each labor-delivery-recovery room shall have readily available:
(a) Separate handwashing unit with hands free controls.
(b) Resuscitation medications and equipment for both mother and infant.
(c) Electronic fetal monitoring equipment.
(d) Oxygen and suction capabilities for the infant.
(e) Bassinet.
(f) Standard infant warming device.
(g) Equipment for the care of the newborn during the time period he/she remains in the labor-delivery-recovery room, as specified by hospital policy.
(h) Infant identification materials.
(2) All equipment and medications for labor, delivery, anesthesia and resuscitation may be portable but shall be present in the room at the time of delivery.

(H) All facilities, furnishings and equipment shall be washable.

130.622: Labor-delivery - Recovery-postpartum Room (Single Room Maternity Care)

(A) There shall be written policies and procedures for the labor-delivery-recovery-postpartum room that shall include, at a minimum, provisions for the following:
(1) Admission criteria.
(2) Criteria for transfer to the cesarean/delivery room.
(3) Restriction of anesthesia to local or regional modes.

(B) The labor-delivery-recovery-postpartum room may be located outside the labor-delivery suite but shall be within the maternity unit so that the patient may be transferred to the cesarean/delivery birth room without having to pass through other functional areas outside the maternity service and so that infant security is maintained.

(C) Construction of new units or alterations or additions to existing maternal and newborn units begun on or after April 1, 2006 shall provide a minimum of 250 square feet of floor space for each labor-delivery-recovery-postpartum room.

(D) The labor-delivery-recovery-postpartum room shall have single patient occupancy.

(E) The labor-delivery-recovery-postpartum room shall have adequate soundproofing.

(F) Each labor-delivery-recovery-postpartum room shall contain or have access to private toilet and shower or tub facilities. If tub facilities are provided, there shall be at least a three foot clearance on two sides and at the end of the tub.

130.622: continued

(G) Each labor-delivery-recovery-postpartum room shall contain the following:
(1) Nurse call system.
(2) Emergency call or intercommunication system.
(3) Oxygen outlet.
(4) Suction outlet.
(5) Sphygmomanometer with adult stethoscope.
(6) Continuous vital signs monitoring equipment for the mother (when regional anesthesia is used).
(7) Equipment for the administration of local and regional anesthesia when these forms of anesthesia are indicated.
(8) Fetoscope or a means of evaluating fetal heart rate.
(9) Emergency delivery kit.
(10) Clock with sweep second hand.
(11) Adjustable lighting adequate for examinations.
(12) Bed.
(13) Adequate seating for family members.
(14) Functional source of emergency electric power.

(H) (1) Each labor-delivery-recovery-postpartum room shall have readily available:
(a) Separate handwashing unit with hands free controls.
(b) Resuscitation medications and equipment for both mother and infant.
(c) Electronic-fetal monitoring equipment.
(d) Oxygen and suction capabilities for the infant.
(e) Bassinet.
(f) Standard infant warming device.
(g) Equipment for the care of the mother and normal newborn until discharge.
(h) Infant identification materials.
(2) All equipment for labor, delivery, anesthesia and resuscitation may be portable but shall be present in the room at the time of delivery.

(I) All facilities, furnishings and equipment shall be washable.

130.623: Postpartum Unit

(A) Provisions shall be made to accommodate the mother and infant in the same room 24 hours a day as requested by the mother.

(B) Equipment for each room in the postpartum unit shall include at least the following:
(1) Suction and oxygen capabilities.
(2) Availability of resuscitation equipment and emergency medications for both the mother and infant.
(3) Sink with hands-free controls in or adjacent to the room.
(4) Available toilet with sink and shower facilities.
(5) Staff emergency call system.

(C) Construction of new units or alterations or additions to existing maternal and newborn units begun on or after April 1, 2006 shall provide a minimum 124 square feet per bed in multiple bedrooms and 144 square feet in single bedrooms.

130.624: Nursery

(A) Each service shall provide within its nurseries a minimum number of well infant bassinets that equals the number of maternity beds plus one bassinet per well infant nursery to accommodate at-home and enroute births, multiple births, retrotransfers and recovery infants.

A lower number of bassinets may be acceptable, if the licensee demonstrates, through a statistical formula provided by the Department, that a 95% probability is achieved for the availability of bassinets, based on the projected number of births per year and the average length of stay.

130.624: continued

(B) All newborns in the nursery shall at all times be in direct view of personnel accountable for them.

(C) In the normal newborn nursery, each bassinet shall have an average of 24 square feet of floor space with a three foot distance between bassinets. Each bassinet shall be immediately accessible to the aisle.

(D) The environment of the nursery shall provide:
(1) Adequate illumination with a system of variation of light intensities.
(2) Temperature of 72° to 78°F controlled by heating and air conditioning equipment.
(3) Humidity of 30-60% with regularly scheduled monitoring.
(4) Interior finish of off-white or colors that permit detection of cyanosis and jaundice.
(5) Windows, if provided, shall have clear glass and doublepane insulation. Window coverings shall be fire-proof and easy to clean.
(6) Floor finishes shall be washable.

(E) Well infant nurseries shall ensure restricted, secure access. Special care nurseries shall be arranged so that entrance is gained solely through a well-lighted anteroom with provision for a handwashing and gowning area.

(F) At least one sink with hands-free controls shall be provided for every six bassinets.

(G) The nursery shall include appropriate storage space for at least minimum daily quantities of infant care supplies.

(H) Nursery equipment shall include at least the following:
(1) Individual bassinets capable of storing individual supplies of linen and infant care equipment.
(2) Suction, oxygen and compressed air.
(3) Washable infant scales.
(4) Covered receptacles for the disposal of soiled linen, diapers or waste, with removable linings or bags and with foot controls.
(5) Blanket warmer, readily available to the nursery.
(6) Staff emergency call system.

(I) The following shall be readily available to the nursery:
(1) Emergency equipment and medications for infant resuscitation and stabilization prior to transfer.
(2) Oxygen administration capabilities with humidification, blending device and analyzer and oxygen saturation monitor.
(3) Cardio-respiratory monitor with high/low alarm.
(4) Commercially manufactured isolette with air filter or a radiant heat bed.
(5) Refrigerator and freezer for storage of breast milk.
(6) Electric breast pump and collection kits.
(7) Appropriate facilities and necessary equipment for circumcision.
(8) Hearing screening equipment.

130.625: Additional Physical Plant Requirements

(A) Electric outlets shall have a common ground.

(B) Electrical equipment shall be checked for current leakage and grounding adequacy when first introduced and at periodic intervals thereafter, per hospital equipment maintenance policy.

(C) Plugs shall be hospital grade. Adaptors, extension cords and junction boxes shall not be used.

(D) Emergency electrical power shall be available in all areas serving mothers and newborns, including sufficient numbers of emergency electrical outlets to maintain life support systems.

130.626: Infection Control

(A) Each maternal and newborn unit shall have policies incorporating standard precautions as defined in guidelines issued by the *Centers for Disease Control and Prevention*. The guidelines can be found at www.cdc.gov.

(B) Policies and procedures shall include a requirement for staff hand hygiene on arrival in the unit as well as before and after each patient contact.

(C) Infection specific precautions shall be based on the identified or suspected pathogen and its known mode of transmission and shall be applied in accordance with guidance issued by the *Centers for Disease Control and Prevention.*

(D) (1) The maternal and newborn service shall have a plan to manage the mother and/or the infant requiring physical isolation. Mothers and infants may be placed in isolation together 24 hours a day.

(2) (a) The hospital shall define those infections for which separate isolation is required. However, if separate isolation is not provided, the following conditions shall be met:

(i) An adequate number of nursing and medical personnel are on duty and have sufficient time for hand hygiene.

(ii) Sufficient space is available for a four to six foot aisle or area between newborn stations.

(iii) An adequate number of sinks for handwashing are available and conveniently located to the "isolated" patient in each nursery room or area.

(iv) Continuing instruction is given to personnel about the mode of transmission of infections.

(b) When the criteria specified in 105 CMR 130.626(D)(2)(a) are not met or the physician determines separation of the infant is indicated, a separate nursery with handwashing facilities shall be used to house the infant.

(3) Forced air incubators may be used for limited protective or reverse isolation of newborns and infants, *i.e.*, to protect these infants from others who may be infectious. Forced air incubators shall not be relied on as a means of preventing transmission from infected incubator patients to others.

(E) The hospital policy shall establish maternal and newborn service staff dress requirements. At a minimum such policy shall include:

(1) Provision for a clean barrier at the point of infant-caregiver contact.

(2) Requirements for when cover gowns should be used.

(3) A requirement that the hair of personnel shall be restrained in a manner that prevents its coming in contact with the patient.

(F) Personnel assigned to maternal and newborn areas shall have:

(1) Demonstrated immunity to rubella either via rubella titer or physician-documented rubella vaccine received on or after 12 months of age.

(2) Demonstrated immunity to measles (rubeola) either via measles titer, physician-diagnosed disease or physician-documented live measles vaccine received on or after 12 months of age.

(3) Tuberculin skin testing, repeat skin testing, and x-ray follow-up of staff with positive findings as defined by hospital infection control policy. At a minimum staff shall be tested at time of hiring, unless a previously significant reaction can be documented.

(G) Exclusion of personnel with communicable diseases shall be defined by hospital policy and consistent with 105 CMR 300.000: *Reportable Diseases, Surveillance, and Isolation and Quarantine Requirements*.

(H) Policies and procedures for cleaning, disinfecting or sterilization of patient care areas, equipment, supplies and infant linen shall be established, approved and periodically reviewed by the hospital's infection control officer or equivalent.

130.627: Records

(A) Maternal Record. The obstetrics service shall establish and maintain a system for obtaining prenatal records or summaries of records of patients at 24 weeks of pregnancy (with updates as warranted in accordance with hospital policy) and for making them available to the staff of the labor and delivery unit when the patient is admitted for delivery. Such records shall be maintained as part of the mother's permanent record.

In addition to the requirements for all hospital patient records, the mother's record shall include:

(1) Mother's medical and obstetric history including prenatal course.

(2) Antenatal blood serology, Rh factor, blood type, HBsAg test, rubella antibody and Group B streptococcal culture results. In addition, results of maternal HIV testing, if applicable.

(3) Admission obstetrical examination including the condition of both mother and fetus.

(4) Complete description of progress of labor and delivery, signed by the attending physician, or certified nurse midwife, including reasons for induction and operative procedures.

(5) Type of medications, analgesia and anesthesia administered to the patient during labor and delivery.

(6) Signed report of qualified obstetric or other consultant when such service has been obtained.

(7) Names and credentials of all those present during delivery.

(8) Description of postpartal course, including complications and treatments, signed by the attending physician or certified nurse midwife.

(9) Medications, including contraceptives, prescribed at discharge.

(10) Infant's condition at birth including gestational age, weight, Apgar score, blood type, and results of initial physical assessment.

(11) Nursing assessment, diagnosis, interventions and teaching.

(12) Method of infant feeding and infant feeding plan of care and progress and documentation of lactation care and services provided.

(13) If neonatal death occurs, cause of death, assessment of the family's coping mechanisms and plans for follow-up and/or referral of the family.

(B) Newborn Record. In addition to the requirements for all patient records, the newborn record shall include:

(1) Significant maternal diseases.

(2) Mother's obstetric history including estimated date of confinement and prenatal care course.

(3) Maternal antenatal blood serology, typing, Rh factors, rubella antibody titer, coombs test for maternal antibodies if indicated, and prenatal HBsAg test results.

(4) Results of any significant prenatal diagnostic procedures including genetic testing and/or chromosomal analysis.

(5) Complications of pregnancy or delivery.

(6) Duration of ruptured membranes.

(7) Medications, analgesic and/or anesthesia administered to the mother.

(8) Complete description of progress of labor including diagnostic tests, treatment rendered and reasons for induction or operative procedures.

(9) Date and time of birth.

(10) Cause of death if it occurs.

(11) Condition of the infant at birth including Apgar score, resuscitation, time of sustained respirations, description of congenital anomalies, gestational age, head circumference, length, weight, pathological conditions and treatments.

(12) Number of cord vessels and description of any placental anomalies.

(13) Written verification of eye prophylaxis, vitamin K and mandated screening tests, including time and date.

(14) Infant Feeding.

(i) Method of feeding including feeding plan of care.

(ii) Documentation of at least two successful feedings, for both breastfeeding and formula fed infants.

(15) Report of infant's initial medical examination within 24 hours of birth, signed by the infant's attending physician or his/her physician designee.

130.627: continued

(16) Informed consent for circumcision or any other surgical procedures.
(17) Physician progress notes written in accordance with hospital policy.
(18) A report of discharge examination signed by attending physician, certified nurse midwife or pediatric nurse practitioner within 24 hours of discharge.
(19) Nursing assessment, diagnosis, interventions and teaching.
(20) Documentation that hearing screening has been performed, screening results and referral, if any. If a referral is made, the medical record shall document the date, time and location of the follow-up appointment.
(21) Discharge instruction sheet including feeding plan, referrals and follow-up care signed by the infant's practitioner.

130.628: Data Collection and Reporting Systems

(A) Each maternal and newborn service shall develop policies and procedures consistent with Massachusetts General Laws related to maternal and newborn care.

(B) Each maternal and newborn service shall maintain a daily patient care log that documents the information required by the Massachusetts Department of Public Health, Division of Health Statistics and Research annual report.

(C) The death of a pregnant woman during any stage of gestation, labor or delivery or the death of a woman within 90 days of delivery or termination of pregnancy shall be reported within 48 hours to the Department by the hospital in which the death occurs.

(D) Each hospital with a maternal and newborn service and each pediatric hospital with a neonatology subspecialty service shall submit patient-specific data reports that include practice benchmarks such as transfers, retro-transfers, and maternal and newborn medical conditions to the Massachusetts Department of Public Health in accordance with Department guidelines.

(E) Each hospital with a Level III maternal and newborn service shall develop and maintain quality improvement initiatives through participation in the Vermont Oxford Network's Very Low Birth Weight (VLBW) Database and shall make Vermont Oxford Network data reports available to the Department upon request.

130.629: Universal Newborn Hearing Screening Programs

(A) Definitions.

Audiologist shall mean an audiologist licensed by the Commonwealth of Massachusetts pursuant to the Board of Registration of Speech-Language Pathology and Audiology regulations at 260 CMR 1.00 *et seq*., who meets such requirements for additional experience as defined by the Department in the Universal Newborn Hearing Screening Guidelines.

Birth Center shall mean either a free-standing or hospital-affiliated birth center, as defined at 105 CMR 142.000 *et seq*..

Birth Hospital shall mean, for the purposes of regulations regarding universal newborn hearing screening programs in 105 CMR 130.000 *et seq*. and 105 CMR 142.000 *et seq*., a hospital with a maternal and newborn service, as designated by the Department pursuant to 105 CMR 130.000 *et seq*., or a hospital without a maternal and newborn service but with a pediatric service, as designated by the Department pursuant to 105 CMR 130.700 *et seq*., from which an infant may be initially discharged to home.

Hearing Screening shall mean a test to detect hearing thresholds of 30 decibels or greater in either ear in the speech frequency range. The methodology shall be one that is defined as acceptable by the American Academy of Pediatrics and the American Speech and Hearing Association for the purposes of newborn infant hearing screening. The hospital's or birth center's screening outcomes shall meet referral rates established by the Department in the Universal Newborn Hearing Screening Guidelines.

130.629: continued

Newborn Infant shall mean, for the purposes of regulations regarding universal newborn hearing screening programs in 105 CMR 130.000 *et seq*. and 105 CMR 142.000 *et seq*., an infant less than three months of age.

(B) Information and Screening Requirements.

(1) Prior to the hearing screening of a newborn infant, the hospital or birth center shall include information explaining the importance of newborn hearing screening and follow up in materials distributed to parents or guardians.

(a) This information shall be readily available in the major languages as identified through the acute hospital's language needs assessment required under 105 CMR 130.1103(A) and literacy levels of the population served by the maternal and newborn service.

(b) Translation of the information to languages used by a smaller percentage of the obstetrical population shall be provided prior to the hearing screening to the maximum extent possible, but in no event later than discharge.

(c) For a hospital without a maternal newborn service from which a newborn infant may be initially discharged to home, the hospital shall ensure that translation of the hearing screening information is provided to non-English speaking parents or guardians of a newborn infant prior to discharge to the maximum extent possible.

(2) Each birth hospital and birth center shall ensure that a hearing screening is performed on all newborn infants before the newborn infant is initially discharged to home.

(a) If a newborn infant is transferred directly from the birth hospital or birth center to another hospital, the responsibility for screening lies with the hospital from which the infant is initially discharged to home.

(b) By the age of three months, an infant shall receive hearing screening. If an infant cannot be screened by the age of three months due to delayed physiological development or physiological instability as a result of illness or premature birth, the infant shall be screened prior to discharge and as early as physiological development or stability will permit reliable screening.

(3) Such screening shall not be performed if the parent or guardian of the newborn infant objects to the screening based upon sincerely held religious beliefs.

(4) If an infant is not successfully screened or missed a screening prior to discharge, the birth hospital or birth center shall contact a Department approved screening center to make an appointment for a screening.

(5) The birth hospital or birth center shall inform, orally and in writing, a parent or guardian of the newborn infant if the infant was not successfully screened or missed a screening. This information shall also be provided in writing to the newborn infant's primary care physician and the Department through its electronic birth certificate system or such mechanism as specified by the Department.

(a) Such notice shall occur prior to discharge whenever possible, but in any case no later than ten days following discharge.

(b) The birth hospital or birth center so informing the parent or guardian and physician shall provide written information to the parent or guardian and physician regarding appropriate follow-up for an infant who missed a screening or was not successfully screened. This information shall include at a minimum the time and location of the screening appointment that has been scheduled, the telephone number of the screening site, a list of diagnostic test centers approved by the Department, as well as information about the importance of screening and follow-up. The information shall be provided to the parent or guardian in writing in the language understood by the parent or guardian.

(6) If an infant did not pass the hearing screening, the birth hospital or birth center shall contact a Department approved diagnostic test center to make an appointment for a diagnostic test.

(7) The birth hospital or birth center shall inform, orally and in writing, a parent or guardian of the newborn infant if the infant did not pass the screening. This information shall also be provided in writing to the newborn infant's primary care physician as well as to the Department through its electronic birth certificate system or such mechanism as specified by the Department.

(a) Such notice shall occur prior to discharge whenever possible, but in any case no later than ten days following discharge.

130.629: continued

(b) The birth hospital or birth center so informing the parent or guardian and physician shall provide written information to the parent or guardian and physician regarding appropriate follow-up for an infant who did not pass the screening. This information shall include at a minimum the time and location of the diagnostic test appointment that has been scheduled, the telephone number of the diagnostic test site, a list of diagnostic test centers approved by the Department, as well as information about the importance of follow-up. The information shall be provided to the parent or guardian in writing in the language understood by the parent or guardian.

(C) Screening Protocols.

(1) The birth hospital or birth center shall designate a program director who is responsible for the provision of newborn infant hearing screening services. The program director shall be an audiologist, neonatologist, pediatric otolaryngologist, neonatal or perinatal nurse, or pediatrician. The program director may delegate duties related to the oversight of the hearing screening service to appropriately trained staff.

(2) A licensed audiologist shall oversee the provision of screening services and shall train the persons performing the screening.

(3) Within 120 days of the effective date of 105 CMR 130.629, each birth hospital and birth center shall submit to the Department for its approval a protocol for newborn hearing screening. The protocol shall, at a minimum, to the satisfaction of the Department:

(a) Identify the staffing of the program and outline the responsibilities of each staff member;

(b) Describe the training and supervision of screening personnel by a licensed audiologist;

(c) Identify the screening methods and equipment to be used to conduct the screening, including provisions for readily available back-up equipment in the event of an equipment malfunction;

(d) Outline infection control procedures;

(e) Provide samples of information to be provided to parents/guardians regarding the screening, including but not limited to information about coverage of the costs of the screening by third party payers, the potential risks of hearing loss, and the benefits of early detection and intervention;

(f) Outline the procedure for documenting the results of the screening;

(g) Identify the procedure for communicating that the infant did not pass, was unsuccessfully screened or missed the screening to the parent or guardian, primary care physician, and the Department. *See* 105 CMR 130.629(B)(5) and (B)(7);

(h) Describe the training and supervision of individuals with responsibility to inform parents or guardians of screening results;

(i) Identify the procedure to ensure an infant who missed a screening or was unsuccessfully screened will receive a screening. *See* 105 CMR 130.629(B)(4) and (B)(5);

(j) Identify the procedure to ensure the parent or guardian of an infant who did not pass the screening will receive information about follow-up and an appointment for diagnostic services. *See* 105 CMR 130.629(B)(6) and (B)(7);

(k) Identify the procedure for reporting data on an annual basis or as otherwise required by the Department, including but not limited to, number of live births, number of infants screened, number of infants who passed the screening, number of infants who did not pass the screening in the right ear, number of infants who did not pass the screening in the left ear, number of infants who did not pass the screening in both ears, number of infants who missed screening or were unsuccessfully screened, the number of infants referred for diagnostic testing, and the number of parents or guardians who refused screening;

(l) Describe the screening program's Quality Assurance review process; and

(m) Include a provision for the review of hearing screening status in the discharge plan for all newborn infants required at 105 CMR 130.630(E)(2)(e), 130.640(B)(4)(p), 130.650(B)(4)(i), and 130.663 and in the information concerning the condition at discharge or transfer required at 105 CMR 142.504(D)(7).

(4) Prior to implementing a significant change in a hearing screening protocol approved by the Department, a hospital or birth center must request and have received written approval of the change from the Department.

130.630: Level I - Community-based Maternal and Newborn Service

The Level I capabilities include the management of uncomplicated pregnancies and the management of pregnancy complications not requiring the facilities and resources of Level IB, IIA, IIB or Level III services. Provides for the care and management of well newborns, stable infants born at _ 35 weeks gestation, including stable retro-transferred infants not needing Level IB, IIA, IIB or III services.

The Level I Service shall meet all of the General Requirements for Maternal and Newborn Services contained in 105 CMR 130.601 through 130.628 and, in addition, the following:

(A) Collaboration/Transfer Agreements. The Level I service shall establish formal written collaboration/transfer agreements with at least one Level III hospital within geographic proximity and other hospitals to which the service regularly refers patients.

(B) Administration and Staffing.

(1) An obstetrician either certified or an active candidate for certification by the American Board of Obstetrics and Gynecology shall be designated as medical director of the maternal service. The medical director or his/her designee shall be available on-call 24 hours a day.

(2) A pediatrician either certified or an active candidate for certification by the American Board of Pediatrics and experienced in the care of newborns shall be designated as medical director of the newborn service. The medical director or his/her designee shall be available on-call 24 hours a day.

(3) The medical directors of the maternal service and the newborn service shall collaborate in the overall medical management of the maternal and newborn service.

(4) An obstetrician either certified or an active candidate for certification by the American Board of Obstetrics and Gynecology with full privileges shall be available on-call 24 hours a day.

(5) A pediatrician either certified or an active candidate for certification by the American Board of Pediatrics with newborn privileges or board certified or an active candidate for certification by the American Board of Family Practice with newborn privileges shall be available on-call 24 hours a day.

(6) A registered nurse designated by the hospital shall be accountable for the 24 hour nursing management of the Level I service. At a minimum, this nurse shall be baccalaureate prepared (master's preferred) and have at least two years experience in the care of stable newborns.

(7) A registered nurse educator, prepared at the baccalaureate level, shall have dedicated responsibility for coordinating and providing educational and training activities to enhance staff knowledge of relevant procedures and technological advances for staff of the maternal and newborn service.

(C) Services. The Level I Maternal and Newborn Service shall provide the following services:

(1) Social risk assessment and social work services by a licensed social worker(s) with experience in social assessment of high risk perinatal patients (mother/infant dyad), patient education, discharge planning, community follow-up programs, referrals and home care arrangements. These services may be provided by the hospital social service department or through written arrangements with public or private social service agencies.

(2) Nutritional consultation by a dietician registered by the American Dietetic Association and experienced in maternal and newborn nutritional needs available seven days a week.

(3) Medical risk assessment and early identification of high-risk maternal, fetal and newborn patients, including access to or consultation with subspecialty services 24 hours a day.

(4) Emergency management of maternal patients, including the capacity to resuscitate and stabilize the patient prior to transfer. In the event of the need for emergency resuscitation and/or stabilization of the mother, an obstetrician shall be either onsite or called to come in to manage the emergency prior to transport of the mother to a Level II or Level III service.

(5) Emergency management of neonates, including the capacity to resuscitate and stabilize the patient prior to transfer. In the event of the need for emergency resuscitation

and/or stabilization of the infant a pediatrician shall be either onsite or called to come in to manage the emergency prior to transport of the infant to a Level III service. All infants requiring mechanical ventilation shall be transferred to a Level III service.

130.630: continued

(6) Arrangements for emergency transport to Level II and III centers as stipulated in collaboration/transfer agreements. Infants shall be transferred to an appropriate center within geographic proximity except under unusual circumstances such as lack of available bed or by parental request.

(7) Availability of continuous internal and external electronic fetal monitoring and auscultation.

(8) Amniocentesis and ultrasound capabilities.

(9) Blood for transfusions including O negative and fresh frozen plasma 24 hours a day.

(10) Respiratory therapists shall be available on call 24 hours a day.

(11) Radiology services, including portable x-ray and ultrasound on-call 24 hours a day.

(12) Clinical laboratory services, including microchemistry, on-call 24 hours a day.

(13) Care of the retrotransferred stable-growing or recovery infant who does not require the complex medical management needs provided by a Level II or III service.

(14) The following care and services 24 hours a day for infants born in-house and for retrotransfers:

(a) Emergency management including newborn cardiopulmonary resuscitation, and emergent diagnostic placement of umbilical arterial and venous arterial catheter lines.

(b) Neonatal stabilization prior to transfer, including:

(i) oxygen administration and monitoring;

(ii) cardio-respiratory monitoring;

(iii) emergency packed red blood cells and fresh frozen plasma;

(iv) glucose management;

(v) intravenous fluid administration;

(vi) antibiotic administration;

(vii) sepsis evaluation, including lumbar puncture, and blood cultures;

(viii) thermoregulation; and

(ix) provision for parental contact prior to transfer.

(c) Care of the newborn:

(i) intramuscular injections;

(ii) phototherapy;

(iii) thermoregulation;

(iv) fluid management;

(v) infant feeding; and

(vi) pain assessment and management.

(15) Registered pharmacist services with access to neonatal, pediatric and maternal pharmacological resources, at a minimum available by telephone consultation.

(16) Provision for 24-hour access to emergency drugs.

(D) Policies and Procedures. The Level I Maternal and Newborn Service shall develop those policies and procedures listed in 105 CMR 130.601 through 130.628 and the following:

(1) Policies and procedures for consultation with and/or transfer of mother and/or newborn to level II and III facilities:

(a) The policies and procedures for maternal transfer shall encourage the delivery at a Level II or III facility of those mothers who are medically assessed as requiring such level of care or whose newborns are anticipated to require the services offered at such level.

(b) The policies and procedures for maternal transfer shall address the management of premature labor, isoimmunizations, medical complications of pregnancy, as well as antenatal and intrapartal complications of delivery.

(2) Policies and procedures for management of medical and surgical complications of pregnancy that include, at a minimum, maternal diabetes, organic heart disorder and surgical abdomen.

(3) Other policies and procedures as deemed appropriate by the hospital perinatal committee.

Such policies shall be submitted to the Department upon request.

(E) Level IB Service Designation. The services capabilities include the management of uncomplicated pregnancies and the management of pregnancy complications not requiring the facilities and resources of Level IIA, IIB or Level III services.

Provides for the care and management of well newborns, stable infants born at ≥ 35 weeks gestation, including stable retro-transferred infants not needing Level IIA, IIB or III

services.

130.630: continued

A Level I service may be designated as a Level IB service with a continuing care nursery service if the requirements of 105 CMR 130.630(E)(1) through (5) are met 24 hours a day, seven days a week:

(1) Administration and Staffing.

(a) A physician certified by the American Board of Pediatrics with experience in the care of special care newborns shall be designated as the medical director of the Level IB Continuing Care Nursery Service. The medical director or his/her designee shall be available on-call 24 hours a day.

(b) A physician who is either certified or an active candidate for certification by the American Board of Pediatrics with Continuing Care Nursery privileges shall be available on-call 24 hours a day.

(c) Nursing.

(i) The hospital shall designate a registered nurse who has responsibility and accountability for the 24 hour nursing management of the Continuing Care Nursery service. At a minimum, such nurse shall be baccalaureate prepared (master's preferred) and have additional education in the specialty area. She or he shall have at least two years experience in the specialty area and meet the qualifications for the management position as defined by hospital policy.

(ii) The hospital shall provide a baccalaureate prepared nurse educator with dedicated responsibility for coordinating and providing education activities to enhance staff knowledge or relevant procedures and technological advances for staff of the maternal and newborn service.

(d) A respiratory therapist with pediatric experience trained in neonatal transition and disease pathology (*e.g.* NRP) shall be present in-house to provide consultation on oxygen therapy and equipment maintenance.

(e) A medical engineer shall be responsible for the maintenance and safe functioning of specialized equipment per written hospital policy.

(2) Services. For designation as a Level IB Continuing Care Nursery Service, the hospital shall provide Level I care and services in addition to the following Level IB care and services 24 hours a day, seven days a week:

(a) Continuous oxygen administration and short term oxygen therapy via nasal cannula and/or oxyhood.

(b) Umbilical artery and vein line insertion and maintenance, and maintenance of peripheral inserted central catheter (PICC).

(c) Long term antibiotic therapy via PICC.

(d) Gavage feedings.

(e) Management of mild apnea of prematurity.

(f) Continuous involvement of parents in infant's care and opportunity for parents to room-in for predischarge education in caring for the infant.

(g) Where indicated, a plan for positive infant stimulation including but not limited to tactile, kinesthetic, auditory and visual measures such as rocking, touching, and vocalization to support positive and reciprocal interaction between infant and parents.

(h) Written discharge planning.

(i) Radiology, including portable x-ray 24 hours a day. Access to radiologist on staff, available daily to interpret neonatal studies, such as chest and abdominal radiographs and cranial ultrasounds.

(j) In-house clinical laboratory services including microchemistry 24 hours a day.

(k) Respiratory therapy services, in-house 24 hours a day.

(l) Access to an ophthalmologist with experience diagnosing conditions such as retinopathy of prematurity.

(m) Access to the services of a developmental specialist.

(3) Policies and Procedures for Transfer. The Level IB Continuing Care Nursery shall have written policies and procedures for the following:

(a) consultation with and/or transfer to a Level II or III unit. All infants requiring mechanical ventilation shall be transferred to a Level III unit,

(b) the circumstances when the presence of a pediatrician designated to be responsible for newborn resuscitation and stabilization is required. A pediatrician with sole responsibility for resuscitation shall be present during the delivery of an infant anticipated to require stabilization and during the period awaiting actual transfer of the infant to a Level II or III facility.

130.630: continued

(4) Other Policies and Procedures. The Level IB Continuing Care Nursery shall have written policies and procedures for the following:

(a) Nursing orientation and ongoing education including theory and skills required to function in the Level IB Continuing Care Nursery.

(b) If therapeutic formulas are made on-site, preparation and sealing of containers to prevent tampering.

(c) Policy and procedures for the care and management of infants with mild apnea of prematureity, neonatal abstinence assessment and management, care and management of PICC line and oxygen therapy, feeding protocols, criteria for neonatology consult and transfer to level III service.

(d) Other policies and procedures as deemed appropriate by the hospital perinatal committee.

130.640: Level IIA and IIB: Community-based Maternal and Newborn Service with a Special Care Nursery

(A) Level IIA Service. Level IIA capabilities include the management of uncomplicated pregnancies and the management of pregnancy complications not requiring the facilities and resources of Level IIB or Level III services. Level IIA capabilities include the care and management of the stable to moderately ill neonate: well newborns, premature infants ≥ 34 weeks gestation, and infants who require special care services (including retro-transferred infants).

A service shall be eligible for designation as a Level IIA service with a special care nursery if one of the following conditions is met:

(1) the service has a minimum of 1,500 births per year in any one of the past three years prior to the initiation of the service designation request; or

(2) the service has satisfactorily demonstrated to the Department that a minimum volume of 1,500 births per year will be reached in the next three years; or

(3) the service has satisfactorily demonstrated to the Department that the hospital meets Level IIA quality and competency requirements and therefore the designation is warranted.

Following the designation, a Level IIA service shall maintain a minimum volume of 1,500 births or the requirement of 105 CMR 130.640(A)(3).

(B) Level IIB Service. Level IIB capabilities include the care and management of uncomplicated pregnancies and the management of pregnancy complications not requiring the facilities and resources a Level III service. Level IIB capabilities include the care and management of the stable to moderately ill neonate, well newborns, premature infants delivering at ≥ 32 weeks gestation, and infants who require special care services (including retro-transferred infants). In compliance with Department guidelines, Level IIB services include the care of infants requiring Continuous Positive Airway Pressure (CPAP).

A service shall be eligible for designation as a Level IIB service with special care nursery if one of the following conditions is met:

(1) the service has a minimum of 2,000 births per year in any one of the past three years prior to the initiation of the service designation request; or

(2) the service has a minimum volume of 2,500 births for each of the two years after the designation as a Level IIA services; or

(3) the service has satisfactorily demonstrated to the Department that the hospital meets Level IIB quality and competency requirements and therefore the designation is warranted.

Following the designation, a Level IIB service shall maintain a minimum volume of 2,000 births or the requirement of 105 CMR 130.640(B)(3).

(C) The Level IIA or IIB Community-based Maternal-Newborn Service shall meet the requirements contained in 105 CMR 130.601 through 130.628 and 105 CMR 130.640(D) through (E).

(D) Maternal Service.

(1) Collaboration/Transfer Agreements. Each Level IIA or IIB service shall establish formal written collaboration/transfer-agreements with at least one Level III hospital with maternal services.

130.640: continued

(2) Administration and Staffing.

(a) A physician certified by the American Board of Obstetrics and Gynecology shall be designated medical director of the maternal service. This physician shall collaborate with the pediatrician responsible for newborn patients in the medical management of the entire maternal and newborn service.

(b) A physician certified or an active candidate for certification by the American Board of Obstetrics and Gynecology with full privileges shall be available on-call 24 hours a day.

(c) Nursing.

1. The hospital shall designate a registered nurse who has responsibility and accountability for the 24 hour nursing management of the maternal service. At a minimum, such nurse shall be prepared at the baccalaureate level and have additional education in the specialty area. She or he shall also have at least two years experience in the specialty area and meet the qualifications for the management position as defined by hospital policy.

2. In a Level IIA service, a registered nurse educator, prepared at the baccalaureate level (master's preferred) shall have dedicated responsibility for coordinating and providing education activities to enhance staff knowledge of relevant procedures and technological advances for staff of the maternal and newborn service.

3. In a Level IIB service, at a minimum a full time master's prepared clinical nurse, preferably a specialist with clinical experience in perinatology or neonatology or a neonatal nurse practitioner shall be available with dedicated responsibility for coordinating education for maternal and newborn staff.

(d) A licensed social worker with experience in maternal and child health shall be available to provide services to mothers.

(e) A dietician registered by the American Dietetic Association and with expertise in maternal care shall be available for consultation to both normal and high-risk mothers.

(3) Services. Each Level II Maternal Service shall provide the following:

(a) Social risk assessment and social work services by a licensed social worker(s) with experience in social assessment of high risk perinatal patients (mother/infant dyad), patient education, discharge planning, community follow-up programs, referrals and home care arrangements.

(b) Nutritional consultation by a registered dietician experienced in maternal and newborn nutritional needs available seven days a week.

(c) Medical risk assessment, resuscitation and stabilization of the mother prior to transport to a Level III facility if required.

(d) Availability of continuous internal and external electronic-fetal monitoring and auscultation.

(e) Blood for transfusions, including O negative and fresh frozen plasma, 24 hours a day.

(f) Radiology, in-house, 24 hours a day.

(g) Clinical laboratory services including in-house capabilities for microchemical fetal blood sample monitoring 24 hours a day.

(h) Capability to perform ultrasound and amniocentesis in-house 24 hours a day.

(i) Subspecialty services for the mothers including, but not limited to, general surgery, cardiology, urology, internal medicine, hematology and neurology.

(j) Access to genetics counseling.

(4) Policies and Procedures. Each Level II Maternal Service shall have written policies and procedures as required by 105 CMR 130.601 through 130.628 and, in addition, the following:

(a) An organized plan for a team approach to deliveries that requires the presence of a pediatrician and an anesthesiologist in the delivery room and properly defines their responsibilities. The hospital's perinatal committee shall establish policies, definitions, and conditions of delivery requiring a team approach.

(b) Policies and procedures for consultation with specialists for medical management and/or transfer of the mother to a Level III facility.

(i) Policies and procedures for maternal transfer shall address the management of premature labor, medical complications of pregnancy, as well as antenatal complications of delivery.

130.640: continued

(ii) Policies and procedures for management of medical and surgical complications of pregnancy shall include but not be limited to maternal diabetes, iso-immunization, organic heart disease and surgical abdomen.

(iii) The policies for maternal transfer shall encourage the delivery at a Level III facility of those mothers who are medically assessed as requiring such level of care or whose newborn(s) are anticipated to require the services of such level.

(c) Other policies and procedures as deemed appropriate by the hospital perinatal committee.

Such policies shall be submitted to the Department upon request.

(E) Special Care Nursery.

(1) Collaboration/TransferAgreements. Each hospital providing a Level II maternal and newborn service shall establish formal written collaboration/transfer agreements with at least one Level III hospital.

(2) Administration and Staffing.

(a) A physician certified by the American Board of Pediatrics who has qualified to appear for the neonatology board shall be designated the medical director of the Special Care Nursery. A pediatrician meeting the requirements of 105 CMR 130.640(E)(2)(b) shall be designated to act in the absence of the director.

(b) A neonatologist who is either certified or an active candidate for certification in neonatology by the American Board of Pediatrics shall be available on-call 24 hours a day.

(c) The hospital shall designate a registered nurse who has responsibility and accountability for the 24 hour nursing management of the Special Care Nursery service. At a minimum, such nurse shall be baccalaureate-prepared and have additional education in the neonatology specialty area. She or he shall have at least two years experience in the specialty area and meet the qualifications for the management position as defined by hospital policy.

(d) A masters-prepared social worker with a background in maternal and child health shall be available as needed.

(e) A dietician registered by the American Dietetic Association and with pediatric experience shall be available as needed.

(f) A respiratory therapist with pediatric experience shall be present in-house 24 hours a day to provide consultation on oxygen therapy and equipment maintenance.

(g) A medical engineer shall be responsible for the maintenance and safe functioning of specialized equipment per written hospital policy.

(3) Special On-site Staffing Requirements. Each hospital providing special care nursery services shall provide on-site coverage 24 hours a day by either a neonatologist or a pediatrician who meets the requirements of 105 CMR 130.640(E)(3)(a) or neonatal nurse practitioner who meets the requirements of 105 CMR 130.640(E)(3)(b), who shall be immediately available to the special care nursery and the delivery room.

(a) Pediatricians. A pediatrician qualified to provide on-site coverage in the special care nursery shall be either a pediatric resident who, at a minimum, has completed the first year of post-graduate residency training with at least two months neonatal intensive care unit rotations or a pediatrician who is certified or an active candidate for certification by the American Board of Pediatrics. Pediatricians shall meet the hospital's requirements for special care nursery privileges. Pediatric residents shall meet criteria for special care nursery coverage established by the Director of the special care nursery. At a minimum, criteria for privileges and coverage shall include the specific clinical skills to provide emergency newborn resuscitation in the delivery room and essential special care nursery skills such as intubation, emergency pneumothorax management, umbilical artery catheterization, and drawing arterial blood gases. Before assignment to provide on-site coverage, pediatricians and residents shall successfully complete the American Heart Association/American Academy of Pediatrics neonatal resuscitation course (or an equivalent).

(b) Neonatal Nurse Practitioner.

(i) A neonatal nurse practitioner qualified to provide on-site coverage in the special care nursery shall

a. preferably have a master's degree but at a minimum have a baccalaureate degree,

130.640: continued

b. be certified as a neonatal nurse practitioner by a nationally recognized organization, and

c. be authorized to practice as an advanced practice registered nurse by the Massachusetts Board of Registration in Nursing.

(ii) Before assignment to provide on-site coverage, each neonatal nurse practitioner shall successfully complete the American Heart Association/ American Academy of Pediatrics neonatal resuscitation course (or an equivalent).

(iii) There shall be a planned schedule for the practitioner to rotate regularly to the Level III service with which the Level II service has a collaboration agreement. Rotation to the Level III service shall occur with such frequency as to assure that the neonatal nurse practitioner has the opportunity to maintain skills in the emergency procedures outlined in 105 CMR 130.640(E)(3)(a). At a minimum, the rotation shall occur annually. The practitioner shall be periodically evaluated by both the Level II and Level III services.

(iv) Neonatal nurse practitioners shall be credentialed through the hospital's nursing department and medical staff and function under approved written guidelines for practice. Neonatal nurse practitioners shall also meet the criteria for delivery room and special care nursery coverage established by the director of the special care nursery. Criteria shall include the skills necessary to provide emergency care to newborns as outlined in 105 CMR 130.640(E)(3)(a).

(v) The nurse practitioner providing Level II coverage shall have at least one year's recent experience functioning as a neonatal nurse practitioner on a service that provides high risk obstetrical and neonatal intensive care unit services.

(vi) Neonatal nurse practitioners shall be part of a team providing patient care and not retained only to provide off hour or holiday coverage at the level II service. The schedule for coverage of the delivery room and special care nursery shall reflect that pediatricians and neonatal nurse practitioners who are members of the team share responsibility for covering all shifts and collaborate in the ongoing care of infants and their families and in professional education activities.

(vii) There shall be written policies and procedures outlining the specific criteria for summoning pediatrician or neonatologist back-up coverage for consultation and for on-site assistance in the delivery room and special care nursery.

(4) Services. Each Level IIA or IIB Special Care Nursery shall provide the following:

(a) Social work services.

(b) Nutritional consultation.

(c) Risk-assessment, stabilization and triage to a Level III services.

(d) Provision of a neutral-thermal environment.

(e) Continuous and long-term oxygen administration via nasal cannula and hood, including oxygen saturation monitoring.

(f) Pharmacological treatment of apnea of prematurity.

(g) Capabilities to insert and maintain intravenous therapy for hydration and medication administration 24 hours a day.

(h) Umbilical artery and venous catheter insertion and maintenance.

(i) Continuous electronic cardio-respiratory monitoring.

(j) Blood transfusion capability (exchange transfusion optional).

(k) Naso-gastric, oro-gastric and oro-jejunal feedings.

(l) Sepsis evaluations including lumbar punctures and cultures.

(m) Parenteral nutrition.

(n) Phototherapy.

(o) Continuous involvement of parents in infant's care and opportunity for parents to room-in for pre-discharge education in caring for the infant.

(p) Where indicated, a plan for positive infant stimulation including but not limited to tactile, kinesthetic, auditory and visual measures such as rocking, touching, and vocalization to support positive and reciprocal interaction between infant and parents. (Attention shall also be given to elimination of negative or extraneous environmental stimuli.)

(q) Written discharge planning.

(r) Arrangements for transport between Level II and Level III facilities as stipulated in collaboration/transfer agreements.

130.640: continued

(s) Care of the retrotransferred infant from Level III after the acute phase of illness has passed, including infants who require care for ongoing medical supervision and management. Placement at a Level II facility shall be jointly agreed upon at least by the medical staff responsible for the infant's care at the Level II and Level III facilities.

(t) Radiology, including portable x-ray capabilities, in-house, 24 hours a day.

(u) In-house clinical laboratory services including microchemistry 24 hours a day.

(v) Respiratory therapy services, in-house, 24 hours a day.

(w) Access within the facility or through arrangement with Level III facilities to subspecialty services or consultation with pediatric surgery, neurology, cardiology and genetics.

(5) Policies and Procedures For Transfer.

(a) Each Level IIA or Level IIB Special Care Nursery shall have written policies and/or procedures for consultation with and/or transfer to a Level III unit. All infants in a designated Level II service requiring mechanical ventilation shall be transferred to a Level III Unit. Such policies shall be submitted to the Department upon request.

(b) A mechanical ventilator or CPAP (Continuous Positive Airway Pressure) may be initiated and used in a Special Care Nursery prior to such transfer only when the Medical Director of the Special Care Nursery approves such use and only when all of the following conditions are met:

(i) A neonatologist remains at the infant's bedside at all times.

(ii) A respiratory therapist with experience in neonatal ventilation remains at the infant's bedside at all times.

(iii) The Special Care Nursery is arranging for transport of the infant to the Level III unit.

(iv) The mechanical ventilator is used only while the infant is awaiting the transport.

(6) Other Policies and Procedures. The Special Care Nursery shall have written policies and procedures for the following:

(a) Nursing orientation and ongoing education including theory and skills required to function in the Special Care Nursery.

(b) If therapeutic formulas are made on-site, policies governing preparation and sealing containers to prevent tampering.

(c) Other policies and procedures as deemed appropriate by the hospital perinatal committee.

(7) Records. In addition to meeting the requirements for records contained in 105 CMR 130.627(B), the record of a newborn treated in a Special Care Nursery shall also contain documentation of the following:

(a) Diagnostic and treatment modalities.

(b) Family-infant interactions.

(c) Parents' understanding of infant's condition, progress and treatment.

(d) Parent education and involvement in both normal and specialized care-giving.

(e) Where indicated, the plan for and patient response to infant stimulation program.

(f) Referrals to community agencies such as parent support groups, visiting nurse associations and early intervention programs.

(8) Environment and Equipment. The Special Care Nursery shall contain the following:

(a) Incubators.

(b) Cardio-respiratory monitors with high/low alarm.

(c) Warming table(s).

(d) Infusion pumps.

(e) Oxygen humidification and warming system. (The respiratory therapist shall check machine functioning and provide scheduled maintenance per written hospital policy.)

(f) Oxygen analyzer.

(g) Umbilical artery/vein catheterization equipment.

(h) Emergency medications and equipment.

(i) A separate formula preparation area if therapeutic formulas are made on-site. The preparation area shall have a work counter, sink for handwashing and storage facility.

(j) Availability of hospital grade breast pump and collection kits in numbers sufficient to meet needs and separate refrigerator/freezer for expressed breast milk.

(9) Construction and Arrangement of Special Care Nursery. The construction and arrangement of the Special Care Nursery shall permit immediate observation and accessibility of infants to personnel. Total nursery space, exclusive of anteroom, shall provide an average floor space of 50 square feet for each incubator or bassinet.

130.650: Level III Maternal and Newborn Service or a Freestanding Pediatric Hospital with Neonatal Subspecialty Services

(A) Level III Service. The Level III maternal and newborn service has the capabilities to provide care for stable to severely ill neonates: well newborns, premature infants, and infants who require neonatal intensive care services. The service provides newborn care to patients with routine medical needs, as well as to those with actual medical problems. The maternal service has the capabilities to manage complex maternal conditions with the expertise of a Critical Care Obstetrics Team.

(B) A service shall be eligible for designation as a Level III service with a neonatal intensive care nursery if one of the following conditions is met:

(1) the service has a minimum of 2,000 births per year in any one of the past three years; or

(2) the service has satisfactorily demonstrated to the Department that a minimum volume of 2,000 births per year will be reached in the next three years; or

(3) the service has satisfactorily demonstrated that the percent of low birth weight infants (< 2,500 grams) delivered is no less than 10% of the annual births.

(C) The Level III service shall meet the requirements contained in 105 CMR 130.601 through 130.628 and, in addition, the requirements set forth in 105 CMR 130.650(D) and (E).

(D) Maternal Service.

(1) Administration and Staffing.

(a) A physician certified by the American Board of Obstetrics and Gynecology with a subspecialty (special competency) in maternal-fetal medicine shall be designated medical director of the maternal service. This obstetrician shall collaborate with the neonatologist responsible for the neonatal intensive care unit in the medical management of the maternal and newborn service.

(b) A physician certified or an active candidate for certification by the American Board of Obstetrics and Gynecology with full privileges shall be available in-house 24 hours a day.

(c) An obstetrician in training who has completed the second year of post-graduate residency shall be immediately available to the unit, in-house, 24 hours a day.

(d) The hospital shall designate a registered nurse who has responsibility and accountability for the 24 hour a day nursing management of the Level III Maternal Service. At a minimum, such nurse shall be master's-prepared and have additional education in the maternal specialty area. She or he shall also have at least five years of clinical experience, two of which are in the specialty area, and, in addition, meet the qualifications for the position as defined by hospital policy.

(e) Qualified registered nurses shall be on duty to care for maternal patients 24 hours a day. The team of nurses shall demonstrate competencies in critical care and be Advanced Cardiac Life Support certified.

(f) A full time master's prepared nurse, preferably a clinical nurse specialist with clinical experience in neonatology or perinatology or a neonatal nurse practitioner, shall be available with dedicated responsibility for coordinating the in-service education for maternal and newborn staff.

(g) A master's-prepared licensed social worker with experience in assessment of perinatal patients (mother/infant dyad), education, discharge planning, community follow-up programs, referrals and home care arrangements shall be available as needed to meet patients' needs.

(h) A dietician registered by the American Dietetics Association with expertise in both normal and high risk maternal and newborn nutritional needs and with access to neonatal nutritional resources shall be available seven days a week.

(2) Services. The Level III Maternal Service shall provide the following:

(a) Social work services.

(b) Nutritional consultation.

(c) Medical risk assessment and resuscitation.

(d) Availability of continuous internal and external electronic-fetal monitoring.

(e) Blood for transfusions, including O negative and fresh frozen plasma, 24 hours a day.

130.650: continued

(f) Anesthesia, in-house, 24 hours a day.
(g) Radiology and imaging, in-house, 24 hours a day.
(h) Clinical laboratory services including on-unit capabilities for microchemical fetal blood sample monitoring 24 hours a day.
(i) 24 hours a day capability for ultrasound and amniocentesis.
(j) Access within the facility or through referral to another Level III facility to intrauterine transfusions and surgery.
(k) Adult subspecialty services including general surgery, thoracic surgery, neurosurgery, cardiology, urology, internal medicine, hematology, neurology, genetics and psychiatry.
(l) Intensive care unit services and invasive cardio-vascular monitoring.

(3) Policies and Procedures. In addition to the policies and procedures required pursuant to 105 CMR 130.601 through 130.628 the level III Maternal Services shall develop policies and procedures for the following:
(a) Admission and transfer criteria.
(b) Maternal/fetal research.
(c) Other policies and procedures as deemed appropriate by the hospital perinatal committee.
Such policies and procedures shall be submitted to the Department upon request.

(E) Neonatal Intensive Care Unit.

(1) Administration and Staffing.
(a) A board-certified neonatologist shall be designated the medical director of the Neonatal Intensive Care Unit. The medical director or his/her designee shall be available on-call 24 hours a day.
(b) A board certified neonatologist or an active candidate for certification in neonatology by the American Board of Pediatrics shall be available in-house 24 hours a day.
(c) A pediatrician-in-training who has completed the second year of post-graduate residency shall be present in-house and immediately available to the unit, 24 hours a day.
(d) A nurse designated by the hospital shall be responsible for the 24 hours a day nursing management of the neonatal intensive care service. At a minimum, this nurse shall be masters-prepared and have experience and advanced education in caring for sick newborns. She or he shall have at least five years of clinical experience, two of which are in the specialty area, and, in addition, meet the qualifications for the position as defined by hospital policy.
(e) Qualified registered nurses shall be on duty to care for neonates 24 hours a day. The team of nurses shall demonstrate competencies in critical care and be Advanced Cardiac Life Support certified.
(f) A freestanding pediatric hospital with a neonatology subspecialty shall meet the requirements for a nurse educator stipulated in 105 CMR 130.650(D)(1)(f).
(g) A masters-prepared licensed social worker with experience in assessment of perinatal patients (mother/infant dyad), education, discharge planning, community follow-up programs, referrals and home care arrangements shall be available as needed to meet patients needs.
(h) A dietician registered by the American Dietetics Association who has expertise in both normal and high risk maternal and newborn nutritional needs and with access to neonatal nutritional resources shall be available seven days a week.
(i) A respiratory therapist trained in the neonatology specialty area shall be available to the unit 24 hours a day.
(j) A medical engineer shall be responsible for the maintenance and safe functioning of specialized equipment per written policy.
(k) A lacatation consultant shall be available seven days a week. Lactation consultants shall have training and experience in providing care and services to infants with special needs and their families.

130.650: continued

(2) Services. The Neonatal Intensive Care Unit shall be located within either a hospital with Level III Maternal and Newborn Service or a Freestanding Pediatric Hospital with Neonatal Subspecialty Services.

The Level III Neonatal Intensive Care Unit shall provide the following:

(a) Access to emergency transport team for transferring sick newborns from the birth hospital to the neonatal intensive care unit.

(b) Ventilatory assistance and/or complex respiratory management including high-frequency ventilation.

(c) Capability of continuous intravenous administration of vasopressor agents.

(d) Insertion and maintenance of all types of venous and arterial lines.

(e) Nitric oxide therapy.

(f) Phototherapy.

(g) Exchange transfusions.

(h) Continuous cardio-respiratory monitoring including oxygen saturation monitoring.

(i) Complex nutritional and metabolic management including total parenteral nutrition.

(j) Full range of emergency pediatric radiology and subspecialty services available 24 hours a day.

(k) Full range of laboratory services including microchemistry and full service blood bank available 24 hours a day.

(l) Access to emergency surgical interventions in the neonate (or written agreements with other institutions providing subspecialty surgical procedures) available 24 hours a day.

(m) Post-surgical care.

(n) Access to pediatric subspecialty consultation and services including surgery, neurology, cardiology, gastroenterology, infectious disease, hematology and genetics available 24 hours a day.

(o) Where indicated, a developmental plan including, but not limited to tactile, kinesthetic, auditory and visual measures such as rocking, touching, and vocalization to support positive and reciprocal interaction between infant and parents. (Attention shall also be given to elimination of negative or extraneous environmental stimuli and to pain management and monitoring.)

(p) Availability of developmental consultation, including occupational and physical therapies.

(q) Continuous involvement of parents in infant's care and opportunity for mothers to room-in for pre-discharge education in caring for the infant.

(r) Crisis-oriented support and ongoing psychosocial services including social work service and the availability of psychiatric consultation for the parents. (Provision for parent support group is recommended.)

(s) Ongoing written discharge planning.

(t) Transport capabilities to return patients to Level I and II units.

(u) Ethics committee for review of complex patient care issues with focus on parental involvement in decision making.

(v) Professional education program.

(w) Availability of educational offerings to collaborating community hospitals.

(x) Parent education appropriate to meet the needs of the infant and family.

(y) Breastfeeding support.

(3) Policies and Procedures. The neonatal intensive care unit shall have written policies and procedures for the following:

(a) Nursing orientation and ongoing education in theory and skills required to function in the NICU.

(b) Admission, transfer and discharge of patients.

(c) Emergency transport of infants from collaborating hospitals. These policies shall require the presence of a physician or neonatology specialty-trained nurse on the transport team and access to telephone consultation with a neonatologist.

(d) Research on infants.

(e) Membership and functioning of the ethics committee.

(f) If therapeutic formulas are made on-site, policies for preparation and sealing of containers to prevent tampering.

(g) Newborn pain management.

130.650: continued

(h) Other policies and procedures as determined by the hospital perinatal committee or the multidisciplianary neonatal intensive care committee.

(4) Records. In addition to meeting the requirements for records contained in 105 CMR 130.627(B), the newborn's record shall also contain documentation of the following:

(a) Diagnostic and treatment modalities.
(b) Family-infant interactions.
(c) Psychosocial evaluation.
(d) Staff-parent communication and parental response to the infant's condition.
(e) Parent education and involvement in both normal and specialized care-giving.
(f) The process used to make decisions where ethical questions are raised, including parental involvement in the process.
(g) Application of research protocols in the care of the infant.
(h) Where need identified, a plan for and patient response to positive infant stimulation program.
(i) Written discharge plans with referrals to community agencies such as parent support groups, visiting nurse associations and early intervention programs.

(5) Environment. The Neonatal Intensive Care Unit shall meet the following requirements:

(a) Sleeping space shall be provided for parents who spend extended periods of time with the infant.
(b) A consultation/demonstration room for private discussions shall be located convenient to the neonatal intensive care unit.
(c) A separate formula preparation area shall be provided when therapeutic formulas are made on-site. The preparation area shall have a work counter, sink for handwashing and storage facility.
(d) Availability of breastfeeding pump room.

(6) Equipment. The Neonatal Intensive Care Unit shall contain at least the following equipment:

(a) Isolettes.
(b) Cardio-respiratory monitors with high/low alarm.
(c) Warming tables.
(d) Infusion pumps.
(e) Oxygen humidification and warming system.
(f) Oxygen analyzer.
(g) Percutaneous oxygen monitor.
(h) Arterial and venous catheterization equipment.
(i) Neonatal resuscitation medications and equipment as described by the American Academy of Pediatrics Neonatal Resuscitation Program guidelines.
(j) Ventilators with heated humidity and alarm systems. (The respiratory therapist shall check machine settings and functioning regularly per departmental policy.)
(k) Transducers for invasive cardiac monitoring.
(l) Immediate accessibility to microchemistry laboratory.
(m) Transport isolette(s).
(n) Electric breast pump(s) and collection kits.
(o) Separate nutrition support area.

130.660: Minimum Lengths of Stay

The minimum length of inpatient stay for mothers and infants shall be 48 hours following a vaginal delivery and 96 hours following a cesarean section. These time periods begin at the time of the infant’s birth. Inpatient stays of less than these time frames shall constitute early discharge. No discharge shall occur between the hours of 8:00 P.M. and 8:00 A.M. without the mother's agreement. Any decision to shorten these minimum stays shall be made by the attending practitioners for both mother and infant in consultation with and upon agreement by the mother. For the purposes of 105 CMR 130.660, attending practitioner shall include obstetrician, pediatrician, family physician, or otherwise qualified attending physician, certified nurse midwife, or nurse practitioner.

130.661: Early Discharge Protocols

Each hospital operating a maternal and newborn service shall develop protocols governing early discharge for mothers and infants. Protocols shall be developed in collaboration with obstetric, pediatric and nursing practitioners, and shall be consistent with guidelines and early discharge criteria set forth by the American College of Obstetricians and Gynecologists (ACOG) and the American Academy of Pediatrics (AAP) and at a minimum shall provide that early discharge may be considered only when the simultaneous discharge of the mother and infant is feasible and only after environmental and other risk factors affecting the well-being of the mother and infant have been assessed. Nothing in 105 CMR 130.661 shall affect the right of a mother to voluntarily choose an early discharge.

130.662: Notices

Mothers shall be informed in writing, at the time of admission and with any pre registration materials, in language understandable to the mother and in their own language, by the hospital, payers or insurers subject to the provisions of St. 1995, c. 218, of their rights under 105 CMR 130.660 through 130.669. The notice shall include, but not be limited to, information about the minimum lengths of inpatient stay of 48 hours following a vaginal delivery and 96 hours following a cesarean section; the right to home visits as provided for in 105 CMR 130.665 following early discharge; and the process and telephone number for filing appeals, if they feel their rights have been violated. Model language for implementation of 105 CMR 130.662 will be provided by the Department.

130.663: Discharge Plans

The hospital shall develop a comprehensive written discharge plan for each mother and newborn for whom an early discharge is contemplated. Said discharge plan, at a minimum, shall identify the mother's and newborn's primary health care providers and specify and arrange for existing, appropriate home care services consistent with ACOG and AAP early discharge guidelines.

130.664: Transfer of Clinical Information

Each hospital operating a maternal and newborn service shall develop protocols for the transfer of pertinent clinical information concerning the mother and infant to the professional or agency providing the home care services. A minimum standard for content should include specific information on the timing and necessity of performing newborn screening as well as information regarding relevant prenatal, birth and hospital postpartum course of care.

130.665: Home Visits

Eligible mothers and infants who participate in early discharge shall be provided, upon agreement by the mother, a minimum of one home visit. The first home visit shall occur within 48 hours following discharge of the mother and infant and shall be conducted by a registered nurse, physician, or certified nurse midwife trained in maternal and infant care. Any subsequent visits determined to be clinically necessary shall be provided by a licensed health care professional or appropriately trained individual under the supervision of a licensed health care professional. Subsequent home visits for the mother and infant shall be based on need as determined by the attending practitioners in consultation with the mother. Minimum content of the first home visit includes review of relevant health history, physical examination of the mother and infant, performance of newborn screening tests, assessment/teaching of maternal self care, infant care, breast/bottle feeding, and the need for social support communication with primary obstetric and pediatric health providers and referral to appropriate follow-up resources. Refusal of any services as specified in 105 CMR 130.665 shall be documented.

130.666: Appeals

Denial of benefits under St. 1995, c. 218 may be appealed to the Department of Public Health. Appeals may be filed by contacting the Department by telephone. The Department shall establish a toll-free telephone number to receive such appeals.

130.667: Notification and Request for Information

Upon receipt of the appeal, the Department shall immediately contact the hospital, post hospital provider, payors or insurers subject to the provisions of St. 1995, c. 218 as appropriate, and may require that portions of the patient's record be immediately furnished to the Department.

130.668: Appeal Decision

Upon review of all relevant information, the Department shall make a determination regarding whether the mother or infant has been denied benefits pursuant to 105 CMR 130.660 through 130.669. Such decision shall be communicated to the patient and to the hospital, post hospital provider, payers or insurers subject to the provisions of St. 1995, c. 218, by telephone immediately following the receipt of all requested information. The Department shall send written confirmation of its decision within a reasonable period of time.

130.669: Stay Pending Appeal

The filing of an appeal shall stay any proposed early discharge of the mother and the infant during the pendency of the appeal.

130.700: Definitions

Terms used in 105 CMR 130.700 shall be interpreted as set forth in 105 CMR 130.700.

General Pediatric Service (Level II), a service which provides care for pediatric patients with uncomplicated and complicated medical and surgical problems who do not require the specialized pediatric intensive care and/or comprehensive specialized services found on a tertiary pediatric service (Level III). A Level II service must have a pediatric unit with suitable personnel and access to subspecialty consultation, supportive laboratory facilities, and ancillary services necessary to provide for the level of care offered.

Pediatric Patient, any inpatient from birth to age 21, other than an infant in a newborn nursery, an intermediate or special care nursery, or a neonatal intensive care unit. Pediatric patients under the age of 15 must be admitted to a pediatric service. Pediatric patients 15 years of age and over may, at the option of the admitting physician, be cared for on a service other than the pediatric service.

130.700: continued

Pediatric Specialty Service, a hospital or a unit of a hospital which limits the pediatric care it provides to a class of diseases or a subdivision of a department of medicine or surgery.

Pediatric Service, the combination of personnel, programs, and space needed to provide care for the diagnosis, treatment, and support of pediatric patients.

Pediatric Unit, the discrete area and equipment designated for the use of pediatric patients.
Tertiary Pediatric Services (Level III), a service which includes Level II pediatric care, pediatric intensive care, and comprehensive specialized services. A Level III service must have a wide range of pediatric specialists and subspecialists, 24-hour in-hospital medical coverage by physicians at a minimum in a pediatric residency program, appropriate pediatric laboratory facilities, and a medical school affiliation.

Uncomplicated Pediatric Service (Level I), a service which provides short-term acute care and/or stabilization for pediatric patients, and which may provide prolonged care to pediatric patients in appropriate cases. A Level I service may perform emergency and selected elective pediatric surgical procedures requiring general or spinal anesthesia in accordance with guidelines developed by the Department in conjunction with the Pediatric Advisory Committee. A Level I service need not have a pediatric unit but it must admit all pediatric patients under 15 years of age to a room or rooms designated primarily for the use of pediatric patients. A Level I service shall exist only in an area where there is documented evidence of geographic isolation as defined in the acute care hospital component of the currently approved state health plan.

130.710: Department Establishment of Pediatric Advisory Committee

The Department shall establish a Pediatric Advisory Committee to advise the Department on issues related to 105 CMR 130.700 through 130.760 (Pediatric Services). This committee's membership shall be multidisciplinary. It shall include but not necessarily be limited to one or more members of the following groups: physicians, nurses, hospital administrators, and consumers. It shall be representative of the various parts of the state and all levels of pediatric care.

130.711: Department Designation of the Level of Pediatric Service in a Hospital

The Department shall designate the level of pediatric service of each hospital subject to Department licensure which has a pediatric service. The Department will base such designations upon documentation submitted by each such hospital of the nature of its pediatric service, followed by a survey of the service by Department staff and consultation with the Pediatric Advisory Committee. By July 1, 1981, each hospital with a pediatric service must file an application with the Department in which it proposes the level of care at which its pediatric services should be designated. This application shall be accompanied by documentation that the hospital's pediatric service complies with the requirements for that level. Thereafter, the Department will survey the hospital to check its compliance with the requirements for that level of care.

130.720: Requirements for all Pediatric Services (Levels I-III)

Pediatric services (Levels I-III) shall comply with the following requirements:

(A) Hospitals providing inpatient care to children under 15 years of age must admit these patients to a level I pediatric area as described in 105 CMR 130.730(C) or a level II pediatric unit or sub-unit, or a level III pediatric unit, with the exception of those patients who require specialized care which cannot be provided in such a pediatric area, unit or sub-unit, such as obstetrics or other care designated by the Department. Pediatric patients 15 years of age and over may, at the option of the admitting physician, be cared for on a service other than the pediatric service.

130.720: continued

(B) (1) Any patient 21 years of age or older may be admitted to a pediatric service when in the opinion of the Chiefs of Pediatrics, and the Director of Nursing or their designees, he has a condition most appropriately treated on a pediatric service.

(2) When a temporary medical emergency fills the medical/surgical service, and the admission to a pediatric unit a sub-unit of certain medical/surgical patients 21 years of age or older poses no danger to pediatric patients, such a medical/surgical patient may be admitted to a pediatric unit or sub-unit with the approval of the Chief of Pediatrics and the Director of Nursing or their designees, provided:

(a) No such patient occupies a bed in the same room as a pediatric patient, and

(b) The hospital keeps a log of each such admission, which is available for the Department's inspection.

(C) Every pediatric service shall establish an advisory multidisciplinary Pediatric Committee, chaired by the Chief of Pediatrics, to advise it on issues related to the service.

(D) Each pediatric service shall have written policies and procedures for patients requiring transfer and/or consultation.

(E) The hospital shall establish a policy identifying which patients must have a consultation by a pediatrician.

(F) Each pediatric service shall develop a policy for the management of infectious disease and isolation.

(G) At least one pediatric patient room shall be available for isolation use.

(H) Each pediatric service shall have written protocols for the management of pediatric patients with known or suspected psychiatric, child abuse or neglect problems.

(I) The pediatric service shall have a policy regarding parental involvement which allows for constant parental support of and contact with the pediatric patient throughout hospitalization. However, parental access to specialized areas like operating rooms may be denied.

(J) The clinical laboratory services available for pediatric patients shall be defined by the Director of Laboratory Services in consultation with the Chief of Pediatrics, the chiefs of other services caring for pediatric patients, and hospital administration.

(K) The diagnostic radiological procedures available for pediatric patients shall be defined by the Chief of Radiology in consultation with the Chief of Pediatrics, the chiefs of other services caring for pediatric patients, and hospital administration.

(L) Equipment sized appropriately for pediatric patients must be available in all areas and services providing care to pediatric patients.

(M) All pediatric service equipment, including beds, cribs, wheelchairs, and toys, shall meet the minimum safety standards established by the hospital's Pediatric Committee.

(N) Provision shall be made for the safe storage of drugs, external solutions, and other potentially toxic substances kept on pediatric services.

(O) Laundry chutes on pediatric services must be locked.

(P) All personnel providing direct care to pediatric patients shall participate in a pediatric orientation program which meets the needs of the hospital and its patients.

130.720: continued

(Q) Each pediatric service shall have pediatric emergency resuscitation equipment and medication readily available. A visible sign or chart listing pediatric doses for emergency drugs shall accompany such equipment.

(R) Only Level III pediatric services may have pediatric intensive care units. Ordinarily, patients under 15 years of age requiring intensive care shall be admitted to pediatric intensive care units in hospitals with Level III pediatric services. When this is inadvisable, such a patient may be admitted to an adult intensive care unit (ICU) if the ICU meets the following criteria for the duration of the pediatric patient's stay:

(1) A physician who is capable of pediatric resuscitation is available in-hospital 24 hours a day.

(2) There is a consultation with a board qualified or certified pediatrician for every pediatric patient under 15 admitted to the ICU.

(3) A registered nurse with clinical pediatric experience is available to the ICU for nursing consultation and/or care whenever a pediatric patient requires it.

(4) Emergency pediatric drug dosages are available in the ICU.

(5) Pediatric-sized emergency resuscitation equipment is available in the ICU.

(6) Emergency laboratory services utilizing microtechniques shall be available in-hospital 24 hours a day.

(7) A radiology technician shall be available in-hospital 24 hours a day.

(S) Every pediatric service shall make available informational material on chronic and other related conditions to families of pediatric patients with such conditions, and services to such families.

(T) Every pediatric service admitting a newborn infant, as defined under 105 CMR 130.629, from either another hospital, birth center, or home, shall verify that the newborn hearing screening has been conducted by the hospital or birth center from which the newborn infant has been transferred or where the newborn infant was born and, in the event it has not been conducted, shall ensure that the screening is performed prior to discharge of the newborn infant, in a manner consistent with standards established by the Department under 105 CMR 130.629.

130.730: Requirements for Uncomplicated Pediatric Services (Level I)

Uncomplicated pediatric services (Level I) must meet the following requirements in addition to those listed in 105 CMR 130.720:

(A) A physician with pediatric experience shall be designated as the Chief of Pediatrics. The Chief of Pediatrics or the Chief's designee shall be on call at all times for the care of pediatric patients.

(B) There must be a registered nurse with clinical pediatric experience on duty 24 hours a day for the direct supervision of pediatric nursing care.

(C) There must be specific beds within an adult care unit designated for pediatric patients. These beds and other equipment must be adaptable for pediatric patients under 15 years of age. The area must be equipped with bathroom facilities for the exclusive use of pediatric patients.

(D) Social services for pediatric patients shall be available in-hospital or through consultant arrangements and their existence must be made known to the families of pediatric patients.

(E) At a minimum, consultant arrangements shall be made for the provision of physical and occupational therapy for pediatric patients.

130.740: Requirements for General Pediatric Services (Level II)

General pediatric services (Level II) must meet the following requirements in addition to those listed in 105 CMR 130.720:

130.740: continued

(A) The hospital must have either:

(1) a discrete unit designated for pediatric patients, or

(2) a discrete sub-unit within an adult care unit containing beds permanently designated as pediatric beds, provided this sub-unit meets the following requirements:

(a) Such pediatric beds are located in a specific room, or contiguous specific rooms, and such beds and other support equipment are appropriate for pediatric patients under 15 years of age.

(b) The nursing station or sub-station serving pediatric patients is adjacent to the room(s) containing beds designated for pediatric patients. Observation of these rooms is possible from the nursing station or sub-station.

(c) The pediatric service has written policies specifying the ages and types of diagnoses of patients who may be admitted to the sub-unit for elective and emergency purposes, and the types of procedures that may be performed on them. The hospital has written policies specifying the types of diagnoses that adult patients may not have to be admitted to the adult care unit in which pediatric sub-unit is located. These policies are approved by the Department, with the advice of the Pediatric Advisory Committee, as assuring an adequate standard of care for pediatric patients admitted to the sub-unit.

(d) The pediatric sub-unit is situated in such a way that the flow of adult patients through it is discouraged.

(B) The hospital must have a designated Chief of Pediatrics who is a board qualified or certified pediatrician. The Chief of Pediatrics or one or more physicians designated by the Chief shall be on call at all times for the care of pediatric patients.

(C) There must be a physician trained in pediatric resuscitation available in-hospital 24 hours a day.

(D) Any pediatric residents and interns assigned to a Level II service shall be supervised by a staff pediatrician.

(E) The head nurse or equivalent who has 24-hour responsibility for the direction and supervision of patient care on the general pediatric service shall be a registered nurse, preferably with a B.S. in nursing, and shall have had documented pediatric nursing experience within the past five years.

(F) At least one registered nurse with pediatric nursing experience shall be assigned to work in each pediatric unit or sub-unit at all times. Nursing personnel regularly assigned to the pediatric unit or sub-unit shall have this as their primary patient care responsibility.

(G) Social services for pediatric patients must be available in-hospital or through consultant arrangements, and their existence must be made known to the families of pediatric patients.

(H) Physical and occupational therapy services shall be available in-hospital or through consultant arrangements.

(I) The Chief of Pediatrics and the Laboratory Director shall determine what laboratory tests, including those utilizing microtechniques, the hospital must have the capacity to perform for pediatric patients. A technician to perform such tests shall be available on a 24-hour basis, in-hospital or on call within l5 minutes.

(J) A radiology technician shall be available on a 24-hour basis, in-hospital or on call within 15 minutes.

(K) When necessary, a registered dietitian shall be available to Level II service staff and the families of pediatric patients for consultation concerning pediatric nutrition.

(L) The hospital shall provide documentation of training and experience in pediatric anesthesiology of anesthesiologists providing care to pediatric patients.

130.740: continued

(M) Pharmacy services including 24-hour availability of medications and intravenous solutions must be available in-hospital. Pharmacy consultations must be available on call 24 hours a day.

(N) The pediatric service must have a protocol for a recreational and educational program sufficient to meet the needs of its patients.

(O) The service must have an area (areas) which is (are) used primarily for recreation or play, and which is (are) equipped with items appropriate for the pediatric patients of the age using the area(s).

130.750: Requirements for Tertiary Pediatric Services (Level III)

Tertiary pediatric services (Level III) must meet the requirements listed in 105 CMR 130.720 and 130.740. In addition, Level III services must meet the following requirements (in case of conflict between these requirements and those listed in 105 CMR 130.740, Level III services must meet the requirements listed in 105 CMR 130.750):

(A) There must be a designated Chief of Pediatrics and an alternate or alternates designated by the Chief who will assume the responsibilities of the Chief in the Chief's absence. Each must be a board qualified or certified pediatrician.

(B) A board qualified or certified pediatrician or pediatric resident with a minimum of two years' residency training must be in the hospital 24 hours a day.

(C) The pediatric service must have a supervisory level nursing coordinator, who has at least a B.S. in nursing and pediatric experience, and preferably an M.S. in pediatric nursing.

(D) At least one social worker with an M.S.W. and experience working with pediatric patients and their families must be assigned to the pediatric service.

(E) Occupational therapy services must be available in-hospital and given or supervised by an occupational therapist with documented experience as a pediatric occupational therapist.

(F) Physical therapy services must be available in-hospital and given or supervised by a physical therapist with documented experience as a pediatric physical therapist.

(G) There must be a board qualified or certified radiologist or a radiology resident in-hospital at all times.

(H) At least one radiologist and one radiology technician in the hospital must have training and experience in pediatric radiology and radiologic technology respectively beyond that required for board certification in radiology and certification in radiologic technology.

(I) There must be a pediatric patient recreation program run by at least one trained activity therapist, whose education and experience is in one or more of the following fields: child development, early childhood education, or early childhood counseling.

(J) Each Level III service must have a pediatric intensive care unit (PICU), discrete from the adult ICU, which is designed and staffed to provide for critically ill or potentially critically ill pediatric patients who need highly specialized intervention and advanced life-support technology. The PICU shall meet the following requirements:

(1) The PICU shall be directed by a board-certified pediatrician, or a pediatric anesthesiologist board-certified in anesthesiology, who has documented special training and experience in the care and management of critically-ill pediatric patients.

130.750: continued

(2) The PICU Director shall be assisted by at least one Associate Director who is a board-certified pediatrician or anesthesiologist with special training and experience in the care and management of critically ill pediatric patients.
(3) A physician who is responsible for the PICU patients shall be in-hospital 24 hours a day.
(4) A person capable of intubating and resuscitating pediatric patients shall be available within or immediately adjacent to the PICU 24 hours a day.
(5) Consultant board-certified physicians with training and experience in the following: pediatric surgery, cardio-thoracic surgery, neurosurgery, and neurology shall be available to the PICU 24 hours a day. Consultants from other subspecialties shall be available as necessary.
(6) The registered nurse in charge of the nursing staff in the PICU shall have at least two years of pediatric nursing experience and documented education in the care and management of critically ill pediatric patients.
(7) Registered nurses in the PICU shall have had documented experience in either clinical pediatric nursing or adult medical/ surgical nursing and shall have received specialized orientation in the care and management of critically-ill pediatric patients prior to assuming PICU staff nurse positions.
(8) The registered nurse/patient ratio in the PICU shall be between 1:1 and 1:2, depending upon the number of nursing care hours required by each patient.
(9) Support personnel necessary to operate, maintain, regulate, or repair monitoring and ventilatory equipment shall be available to the PICU 24 hours a day.

130.760: Requirements for Pediatric Specialty Services

Pediatric specialty services must apply to the Department for designation of the level of their pediatric service pursuant to 105 CMR 130.711. Absent a waiver from the Department, each such service shall comply with all the requirements for the level of care at which it is designated. However, if documentation submitted by the pediatric specialty service, a survey by the Department and Department consultation with the Pediatric Advisory Committee provide substantial evidence that any of these requirements should not apply, on the basis of the grounds for waiver of standards indicated in 105 CMR 130.970, the Department may waive the application of such a requirement to the service.

130.761: Emergency Service - Pediatric Patients

(A) All hospitals providing emergency care for pediatric patients, as defined by 105 CMR 130.701, shall meet the following requirements:
(1) At least one physician with training in pediatric resuscitation shall be on duty in the emergency room at all times.
(2) A pediatrician or a general or family practitioner who regularly sees pediatric patients of all ages shall be on call 24 hours a day and available for consultation in the emergency room within 30 minutes.
(3) The hospital shall have a policy providing for consultation and/or referral from the emergency room to an appropriate pediatric inpatient service.
(4) Equipment and medication necessary for pediatric emergency resuscitation shall be readily available in the emergency room. A readily visible sign or chart listing pediatric doses for emergency drugs shall be posted in all rooms in which resuscitation is conducted.
(5) Names and phone number of consultants on call to provide emergency care to pediatric patients' shall be readily accessible.
(6) Radiology and laboratory services, including appropriately board-certified physicians and technicians, shall be available on call 24 hours a day.
(7) The emergency service shall have written policies and procedures for the management of pediatric problems, including:
(a) Cardiopulmonary resuscitation.

130.761: continued

(b) Respiratory obstruction.
(c) Burns.
(d) Poison and ingestions.
(e) Drug and alcohol abuse.
(f) Child abuse.
(g) Psychiatric disturbances.
(h) Transfer of pediatric patients to other facilities.
(i) Consent to treatment on behalf of pediatric patients.
(j) Handling of special situations such as pediatric patients dead on arrival; or suspected rape, pregnancy, or venereal disease.

(B) Emergency services in hospitals having a tertiary pediatric service (Level III) as defined by 105 CMR 130.705, shall meet the requirements of 105 CMR 130.761(A) and in addition the following requirements:

(1) At least one physician experienced in pediatric emergency care shall be on duty in the emergency care area at all times.

(2) There shall be board qualified or certified physician coverage on call to provide care for any critically injured or ill pediatric patient at all times. This coverage shall include but not necessarily be limited to pediatrics, surgery, and anesthesiology.

(3) Social services and psychiatric services shall be available on call 24 hours a day.

130.770: Contact Person

Acute hospitals shall designate a contact person for receiving all notifications from the Department regarding appeals filed pursuant to 105 CMR 130.666. Said contact person shall immediately make available any patient information requested by the Department.

130.771: Advisory Committee

The Department shall establish an advisory committee, comprised of representatives of the medical, insurance, and consumer communities, so as to advise the Department on matters pertaining to hospital length of stay requirements and post-partum care benefits for mothers and newborns. Such advisory committee shall meet as often as necessary, but no less than once a year, in accordance with procedures established by the Department. The advisory committee shall advise the Department as to the following:

(1) the adequacy and appropriateness of the current ACOG/AAP standards regarding early discharge and post-partum care services.

(2) any matter affecting the implementation of St. 1995, c. 218 or 105 CMR 130.660 through 130.669.

130.800: Hospice Services

Licensing regulations applicable to a hospice service of a hospital are set forth in 105 CMR 141.000: *The Licensure of Hospice Programs*, which are incorporated herein by reference.

130.810: Birth Center Services

Licensing regulations applicable to the birth center services of a hospital set forth in 105 CMR 142.000 which are incorporated herein by reference.

130.820: Definitions

The following definitions apply in 105 CMR 130.820 through 130.836 when used with regard to satellite emergency facilities:

Satellite Emergency Facility (SEF) means a health care facility off the premises of a hospital that is listed on the license of the hospital, at which the hospital is authorized pursuant to 105 CMR 130.820 through 130.836 to accept patients transported to the SEF by ambulance, and which operates on a seven day per week 24 hour per day basis. SEFs must comply with all requirements of the federal Emergency Medical Treatment and Active Labor Act (EMTALA).